FEDERAL REGISTER

Vol. 77 Thursday,
No. 71 April 12, 2012

Pages 21841–22184

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpo@custhelp.com*.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 77 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**
Single copies/back copies:	
Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**
FEDERAL AGENCIES	
Subscriptions:	
Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

FEDERAL REGISTER WORKSHOP

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, May 15, 2012
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741-6008

Printed on recycled paper.

Contents

Federal Register

Vol. 77, No. 71

Thursday, April 12, 2012

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this page for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register

Vol. 77, No. 71

Thursday, April 12, 2012

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 983

[Doc. No. AMS–FV–11–0077; FV11–983–2 FIR]

Pistachios Grown in California, Arizona, and New Mexico; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule that decreased the assessment rate established for the Administrative Committee for Pistachios (Committee) for the 2011–12 and subsequent production years from $0.0007 to $0.0005 per pound of assessed weight pistachios. The Committee locally administers the marketing order which regulates the handling of pistachios grown in California, Arizona, and New Mexico. The interim rule was necessary to allow the Committee to provide sufficient revenue to meet its expenses while maintaining a financial reserve within the limit authorized under the order.

DATES: *Effective Date:* April 13, 2012.

FOR FURTHER INFORMATION CONTACT: Andrea Ricci or Kurt J. Kimmel, California Marketing Field Office, Marketing Order and Agreements Division, Fruit and Vegetable Programs, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Andrea.Ricci@ams.usda.gov* or *Kurt.Kimmel@ams.usda.gov.*

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: *http//www.ams.usda.gov/MarketingOrdersSmallBusinessGuide;* or by contacting Laurel May, Marketing Order Agreement Division, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Laurel.May@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 983, both as amended (7 CFR part 983), regulating the handling of pistachios grown in California, Arizona, and New Mexico, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

Under the order, California, Arizona, and New Mexico pistachio handlers are subject to assessments, which provide funds to administer the order. Assessment rates as issued under the order are intended to be applicable to all assessable pistachios for the entire production year and continue indefinitely until amended, suspended, or terminated. The Committee's fiscal period begins on September 1, 2011, and ends on August 31, 2012.

In an interim rule published in the **Federal Register** on September 29, 2011, and effective on September 30, 2011, (76 FR 60361, Doc. No. AMS–FV–11–0077; FV 983–2 IR], § 983.253 was amended by decreasing the assessment rate established for California, Arizona, and New Mexico pistachios for the 2011–12 and subsequent production years from $0.0007 to $0.0005 per pound of assessed weight pistachios. The decrease in the per pound assessment rate allows the Committee to provide sufficient revenue to meet its expenses while maintaining a financial reserve within the limit authorized under the order.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 900 producers of pistachios in the production area and approximately 25 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration as those having annual receipts less than $750,000 and small agricultural service firms are defined as those whose annual receipts are less than $7,000,000. (13 CFR 121.201) Based on Committee data, it is estimated that over 70 percent of the handlers ship less than $7,000,000 worth of pistachios and would thus be considered small business under the SBA definition. It is also estimated that over 80 percent of the growers in the production area produce less than $750,000 worth of pistachios and would thus be considered small businesses under the SBA definition.

This rule continues in effect the action that decreased the assessment rate established for the Committee and collected from handlers for the 2011–12 and subsequent production years from $0.0007 to $0.0005 per pound of assessed weight pistachios. At its July 21, 2011 meeting, the Committee unanimously recommended 2011–12 expenditures of $681,850 and an assessment rate of $0.0005 per pound of assessed weight pistachios. The assessment rate of $0.0005 is $0.0002 lower than the 2010–11 rate. Applying the $0.0005 per pound assessment rate to the Committee's 400,000,000 pound crop estimate should provide $200,000 in assessment income. Thus, income derived from handler assessments combined with the 2010–11 financial reserve, estimated interest income, and funds received from the CPRB is expected to provide sufficient revenues for the Committee to meet its expenses while maintaining a financial reserve within the limit authorized under the order.

According to NASS, the season average producer price was $1.67 in 2009 and $2.22 per pound of assessed weight pistachios in 2010. A review of historical information and preliminary information pertaining to the upcoming production year indicates that the grower price for the 2011–12 production year could range between $1.67 and $2.22 per pound of assessed weight pistachios. Therefore, the estimated assessment revenue for the 2011–12 production year as a percentage of total producer revenue during the 2011–12 production year could range between 0.030 and 0.023 percent.

This rule continues in effect the action that decreased the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers.

In addition, the Committee's meeting was widely publicized throughout the California, Arizona, and New Mexico pistachio industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the July 21, 2011, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0215 Pistachios Grown in California. No changes in those requirements as a result of this action are anticipated. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large California, Arizona, and New Mexico handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Comments on the interim rule were required to be received on or before November 28, 2011. No comments were received. Therefore, for reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: *http://www.regulations.gov/#!documentDetail;D=AMS-FV-11-0077-0001*.

This action also affirms information contained in the interim rule concerning Executive Orders 12866 and 12988, and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (76 FR 60361, September 29, 2011) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 983

Marketing agreements, Pistachios, Reporting and recordkeeping requirements.

PART 983—PISTACHIOS GROWN IN CALIFORNIA, ARIZONA, AND NEW MEXICO

■ Accordingly, the interim rule amending 7 CFR part 983, which was published at 76 FR 60361 on September 29, 2011, is adopted as a final rule, without change.

Dated: April 6, 2012.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2012–8822 Filed 4–11–12; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 993

[Doc. No. AMS–FV–11–0068; FV11–993–1 FIR]

Dried Prunes Produced in California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule that decreased the assessment rate established for the Prune Marketing Committee (Committee) for the 2011–12 and subsequent crop years from $0.27 to $0.22 per ton of salable dried prunes handled. The Committee locally administers the marketing order for dried prunes produced in California. The interim rule was necessary to allow the Committee to lower its assessment rate because of a substantial decrease in wage and salary expenses. The current excess funds carried forward along with the estimated interest income, combined with the funds generated from the decreased assessment rate and decreased crop is expected to provide adequate income to cover anticipated 2011–12 expenses.

DATES: *Effective Date:* April 13, 2012.

FOR FURTHER INFORMATION CONTACT: Andrea Ricci or Kurt J. Kimmel, California Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Andrea.Ricci@ams.usda.gov* or *Kurt.Kimmel@ams.usda.gov.*

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: *http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide;* or by contacting Laurel May, Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Laurel.May@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 110 and Order No. 993, both as amended (7 CFR part 993), regulating the handling of dried prunes in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

Under the order, California dried prune handlers are subject to assessments, which provide funds to administer the order. Assessment rates issued under the order are intended to be applicable to all assessable California dried prunes for the entire crop year, and continue indefinitely until amended, suspended, or terminated. The Committee's crop year begins August 1, and ends on July 31.

In an interim rule published in the **Federal Register** on August 30, 2011, and effective on August 31, 2011 (76 FR 53813, Doc. No. AMS–FV–11–0068; FV11–993–1 IR), § 993.347 was amended by decreasing the assessment rate established for the Committee for the 2011–12 and subsequent crop years from $0.27 to $0.22 per ton of salable dried prunes handled. The decrease in the per salable ton assessment rate allows the Committee to lower its assessment rate because of a substantial decrease in wage and salary expenses. The current excess funds carried forward along with the estimated interest income, combined with the funds generated from the decreased assessment rate and decreased crop to provide adequate income to cover anticipated 2011–12 expenses.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 800 producers of dried prunes in the California area and approximately 21 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration as those having annual receipts less than $750,000 and small agricultural service firms are defined as those whose annual receipts are less than $7,000,000. (13 CFR 121.201)

Committee data indicates that about 64 percent of the handlers ship under $7,000,000 worth of dried prunes. Dividing the average dried prune crop value for 2010 reported by the National Agricultural Statistics Service (NASS) of $149,860,000 by the number of producers (800) yields an average annual producer revenue estimate of about $187,325. Thus, the majority of handlers and California dried prune producers may be classified as small entities.

This rule continues in effect the action that decreased the assessment rate established for the Committee and collected from handlers for the 2011–12 and subsequent crop years from $0.27 to $0.22 per ton of salable dried prunes. The Committee unanimously recommended 2011–12 expenditures of $46,497 and an assessment rate of $0.22 per ton of salable dried prunes for the 2011–12 crop year. The assessment rate of $0.22 is $0.05 lower than the rate previously in effect. Applying the $0.22 per ton assessment rate to the Committee's 122,000 ton estimate should provide $26,840 in assessment income. Thus, the current excess funds carried forward along with the estimated interest income, combined with funds generated from the decreased assessment rate and decreased crop is expected to provide adequate income to cover anticipated 2011–12 crop year expenses.

This rule continues in effect the action that decreased the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers.

In addition, the Committee's meeting was widely publicized throughout the California dried prune industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the June 16, 2011, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements as a result of this action are anticipated. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large California dried prune handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Comments on the interim rule were required to be received on or before October 31, 2011. No comments were received. Therefore, for reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to *http://www.regulations.gov/#!documentDetail;D=AMS-FV-11-0068-0001*.

This action also affirms information contained in the interim rule concerning the Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. chapter 35), and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (76 FR 53813, August 30, 2011) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 993

Marketing agreements, Plums, Prunes, Reporting and recordkeeping requirements.

PART 993—DRIED PRUNES PRODUCED IN CALIFORNIA

■ Accordingly, the interim rule amending 7 CFR part 993, which was published at 76 FR 53813 on August 30, 2011, is adopted as a final rule, without change.

Dated: April 6, 2012.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2012–8820 Filed 4–11–12; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Document No. AMS–FV–11–0021]

Mango Promotion, Research, and Information Order; Assessment Increase

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the Mango Promotion, Research, and Information Order (Order) to increase the assessment rate on first handlers and importers of mangos from one-half cent per pound to three-quarters of a cent per pound. The increase is permitted under the Order, which is authorized by the Commodity Promotion, Research, and Information Act of 1996 (Act). The National Mango Board (Board), which administers the Order, recommended this action to ensure that the Board's research and promotion programs continue to be adequately funded.

DATES: *Effective Date:* September 1, 2012.

FOR FURTHER INFORMATION CONTACT: Veronica Douglass, Marketing Specialist, Research and Promotion Division, Fruit and Vegetable Programs, AMS, U.S. Department of Agriculture, Stop 0244, Room 1406–S, 1400 Independence Avenue SW., Washington, DC 20250–0244; telephone: 888–720–9917; fax: 202–205–2800; or email: *veronica.douglass@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under the Mango Promotion, Research, and Consumer Information Order (Order) [7 CFR part 1206]. The Order is authorized under the Commodity Promotion, Research, and Information Act of 1996 (Act) [7 U.S.C. 7411–7425].

Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect.

Section 524 of the Act provides that the Act shall not affect or preempt any other State or Federal law authorizing promotion or research relating to an agricultural commodity.

Under the Act, a person subject to an order may file a petition with the U.S. Department of Agriculture (Department) stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and requesting a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, the Department will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of the Department's final ruling.

Regulatory Flexibility Analysis and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities that would be affected by this rule. The purpose of the RFA is to fit regulatory action to scale on businesses subject to such action, so that small businesses will not be disproportionately burdened.

The Small Business Administration defines small agricultural producers as those having annual receipts of no more than $750,000, and small agricultural service firms as those having annual receipts of no more than $7 million (13 CFR part 121). First handlers and importers would be considered agricultural service firms, and the majority of mango producers, first handlers and importers would be considered small businesses. Although this criterion does not factor in additional monies that may be received by producers, first handlers and importers of mangos, it is an inclusive standard for identifying small entities.

First handlers and importers who market or import less than 500,000 pounds of mangos annually are exempt from the assessment. Mangos that are exported out of the United States are also exempt from assessment. In addition, domestic and foreign producers are not subject to assessment under the Order, but such individuals are eligible to serve on the Board along with importers and first handlers. Currently, fewer than five first handlers and 193 importers are subject to assessment under the Order.

Under the current Order, first handlers and importers of 500,000 pounds or more of mangos per year each pay a mandatory assessment of one-half cent per pound of mangos handled or imported. The amendment to the Order would increase the rate of assessment currently paid by first handlers and importers of mangos to three-quarters of a cent per pound. Exempt handlers and importers would remain exempt from assessment. While this amendment will have an economic impact on handlers and importers of more than 500,000 pounds of mangos per year, the impact is expected to be offset by the benefits to the mango industry. Assessment revenue is used by the Board to finance promotion, research, and information programs designed to increase consumer demand for mangos. Assessments at the current rate of one-half cent per pound generate about $3.4 million in annual revenue. The Order is administered by the Board under the Department's supervision.

According to the Board, additional revenue is needed to avoid reductions in the promotions budget and to increase investment in marketing and research programs. At its September 2009 meeting, the Board voted to propose a 50 percent increase in the mango assessment rate upon completion of the March 2010 referendum to determine whether mango handlers and importers favored continuation of the Order. The increase in the assessment rate is consistent with section 1206.42(b) of the Order, which permits modification of the assessment rate by the Board with the approval of the Secretary, after the first referendum is conducted.

Mango assessment collections began on January 3, 2005, however, Board activities did not begin until 2006. Consequently, the Board was able to grow a considerable reserve that was used to supplement annual assessment revenues from 2007 until 2009. In 2010, higher than expected assessment revenue made it possible for the Board to operate without exceeding the total assessments collected for that year and to begin 2011 with approximately $1.6 million in available resources. However, with 2011 spending projected at approximately $4.3 million and assessment income projected at approximately $3.2 million, the Board is expected to begin 2012 with a reserve of $505,244. With no extra funds available from reserves, and if the assessment rate is kept at the current level, the Board's budget would have to be decreased.

In 2010, an econometric study of the effects of the Board's promotion activities on U.S. mango demand was conducted by Dr. Ronald Ward of the University of Florida (2010 economic study). The study indicates that from 2005 through 2009, the value of mango imports to the U.S. grew from $169 million to $217 million. This is significant as the vast majority of mangos consumed in the U.S. are imported. The growth in value is the result of both higher prices and greater volumes imported. The study also found that the Board's activities have had a positive economic impact on the demand for mangos, both in attracting more buyers and in increasing the number of mangos purchased per buyer. According to the study, increased spending by the Board would correspond to increases in market penetration and the number of households purchasing mangos. Likewise, decreased spending would correspond to declines in both of those areas. Based on the analysis of these two factors and the value of mango imports, the study concludes that every $1 invested in the Board adds an additional $7 to mango freight on board revenues. This study is available from the Board and on the Agricultural Marketing Service Web site (*www.ams.usda.gov/fvpromotion*).

An increase of one quarter of a cent per pound in the mango assessment rate is expected to add an additional $1.6 million per year to the Board's assessment revenue. With the additional revenue collected, the Board intends to invest primarily in marketing and research programs. In addition, the Board would be able to establish a contingency fund to ensure consistent funding in the face of market instability.

The Board considered three alternatives prior to recommending that the assessment rate be increased. First, the Board considered reducing investment in its research program. However, postponing research projects, such as the human nutrition studies that may help the Board to develop health messages that increase demand for mangos, could hinder expansion of the U.S. mango market. Second, the Board considered limiting investment in programs designed to improve the quality of mangos available at the retail level. Delivering higher quality mangos to U.S. consumers is one of the Board's top priorities because higher quality often translates to higher demand. Third, the Board considered reducing funding for its marketing programs. Lowering the funding level for marketing programs would significantly reduce the Board's ability to conduct promotion and consumer marketing activities, thereby hindering its efforts to increase demand for mangos.

This rule does not impose additional recordkeeping requirements on first handlers, importers, or producers of mangos. First handlers or importers of less than 500,000 pounds of mangos per year are exempt.

There are no Federal rules that duplicate, overlap, or conflict with this rule. Additionally, section 517(c) of the Act states that not more than one assessment may be levied on a first handler or importer.

In accordance with OMB regulation [5 CFR part 1320] that implements information collection requirements imposed by the Paperwork Reduction Act of 1995 [44 U.S.C. 3501–3520], there are no new requirements contained in this rule. The information collection requirements imposed by the Order have been previously approved under OMB control number 0581–0093. This rule does not result in a change to the information collection and recordkeeping requirements.

Background

Under the Order, the Board administers a nationally coordinated program of research and promotion designed to strengthen the position of mangos in the marketplace and to establish, maintain, and expand U.S. markets for mangos. The program is financed by assessments on first handlers and importers of 500,000 pounds or more of mangos per year. The Order specifies that first handlers are responsible for submitting assessments to the Board on a monthly basis and maintaining records necessary to verify their reporting. Assessments paid by importers are collected and remitted to the Board by the U.S. Customs and Border Protection Service.

This rule increases the mango assessment rate, by one quarter of a cent per pound, to three quarters of a cent per pound. Currently, the assessment rate is one half cent per pound of mangos handled domestically or imported into the United States. In order to sustain and expand its promotion, research, and communications programs, the Board contends that additional revenue is required. The assessment rate increase is expected to generate an additional $1.6 million annually, depending on the volume of mangos handled in the United States or imported into the United States. In 2010, a total of 717,830,404 pounds of mangos were subject to assessment, resulting in approximately $3.6 million in assessment revenue. Less than one percent of the total assessments were from domestic handlers as the vast majority of assessments were collected from importers. The Board states that the assessment rate increase will enable it to make additional investments in its marketing and research programs. In addition, the Board states that some of the additional revenue may be used to establish a contingency fund to ensure consistent funding for its programs.

The Board, whose members represent domestic producers, first handlers, importers, and foreign producers, voted at its September 12, 2009 meeting to increase the assessment rate by one quarter of a cent per pound after the March 2010 continuance referendum. Of the members present at the meeting, 9 voted in favor and 4 opposed proposal of the assessment rate increase. The four Board members who voted against the assessment increase stated that the increase would be passed on to mango producers. The assessment will be imposed on first handlers and importers who pay assessments under the Order. Business decisions on how to manage assessments, including whether to pass back the cost of assessments to producers, are made by handlers and importers based on their respective business practices.

Accordingly, this action will amend the Order by changing the current assessment rate of one half cent per pound of mangos, as stated in section 1206.42(b), to three quarters of a cent per pound.

A proposed rule concerning this action was published in the **Federal Register** on May 10, 2011 [76 FR 26946]. Copies of the proposed rule were made available on the Internet at *www.ams.usda.gov/fvpromotion* and *www.regulations.gov.* In addition, AMS published a press release announcing the comment period. The proposed rule provided a 60-day comment period, which ended July 11, 2011. Twenty comments were received by the deadline.

Summary of Comments

Of the 20 comments received regarding the proposed rule, 17 supported and three opposed the proposed amendment.

A total of 11 commenters supported the assessment rate increase based on positive results already achieved by the Board. Their comments stated that the Board has increased mango consumption and market penetration, fostered better relations between consumers and the mango industry, and educated consumers and industry stakeholders about mangos. One commenter noted that because of the Board's efforts, more than 4,000 in-store mango tasting events have been conducted, the number of restaurants offering mango dishes has grown, more benefits stemming from mango consumption have been discovered, and the mango industry has a united consumer marketing message. Two commenters noted specific support for the Board's health research activities.

Six commenters supported the assessment rate increase as a means of ensuring the Board's programs are adequately funded. Two commenters stated that the Board's programs are essential to maintain the growth in U.S. demand for mangos. One commenter also stated that the proposed increase in assessments is needed to keep up the momentum of the Board's current promotion and research activities. One commenter noted that any additional revenue should be used primarily for promotion and research programs rather than overhead expenses.

One supportive commenter noted that all Board expenditures must be approved by the Board members, who represent the interests of different regions and countries. Because the Board is comprised of members from six countries and the Commonwealth of Puerto Rico, the ability of the Board to come to a consensus on activities and expenditures is valuable to the entire mango industry. One comment cited the geographic diversity of the Board as a key reason for its success because a wide variety of viewpoints are represented by the Board members. The fact that the assessment increase is favored by a majority of Board members demonstrates the breadth of support for the increase from throughout the mango industry.

Another commenter stated that the proposed assessment increase has been discussed with all mango industry stakeholders, and is favored by organizations in Mexico, Peru, Guatemala, Haiti, Ecuador and Brazil. In order to determine whether foreign producers would support an assessment increase, the Board held informational meetings in each of the countries that export mangos to the United States. At these meetings, Board representatives explained the activities conducted with assessment funds and received positive feedback from attendees on the proposed assessment increase.

One of the comments in support of the assessment increase was received from a Mexican mango industry organization. In addition to their own comments, several commenters submitted correspondence from foreign agricultural organizations indicating their support for the assessment increase. Letters of support were received on behalf of organizations in Haiti, Peru, Guatemala, Ecuador, and Brazil.

One commenter opposed the assessment increase, stating that the Board can fulfill its objectives at its current funding level. As the Board stated in its proposal, without an increase in the assessment rate, spending on mango research and promotion programs would need to be reduced. As stated previously, the 2010 econometric study concluded that decreased spending on the Board's programs would correspond to declines in mango purchases.

One commenter opposed the assessment increase, stating that raising the assessment rate would harm mango importers already coping with higher freight rates and poor currency exchange rates. In response, another commenter argued that the assessment is an investment rather than an expense. This same commenter further stated that the investment in the Board would be used to improve market penetration, thereby improving returns to growers and shippers, and offsetting the higher costs. Additionally, the 2010 econometric study found that increased spending by the Board provides a large increase in revenues to importers.

One commenter opposed the assessment increase, stating that the current assessment provides a negative return on investment. Another commenter also noted that the Board should ensure that its investments are yielding reasonable returns. One commenter further stated that the assessment rate needed to sufficiently fund promotion programs would likely be 20 times the proposed rate of three quarters of a cent per pound. No evidence was offered to support this claim. According to the 2010 econometric study, every $1 currently spent by the Board adds an additional $7 to mango freight on board revenues.

The Department has considered all of the comments and is not making any changes to the proposed rule.

After consideration of all relevant material presented, the Board's recommendation, public comments and other information, it is hereby found that this rule, as published in the **Federal Register** on May 10, 2011 [76 FR 26946], is consistent with and will effectuate the purpose of the Act.

List of Subjects in 7 CFR Part 1206

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Mango promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1206 is amended as follows:

PART 1206—MANGO PROMOTION, RESEARCH, AND INFORMATION

■ 1. The authority citation for 7 CFR part 1206 continues to read as follows:

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

■ 2. In § 1206.42, paragraph (b) is revised to read as follows:

§ 1206.42 Assessments.

* * * * *

(b) The assessment rate shall be ¾ of a cent per pound on all mangos. The assessment rate will be reviewed and may be modified by the Board with the approval of the Department, after the first referendum is conducted as stated in § 1206.71(b). The Department will amend this section if the assessment rate is modified.

* * * * *

Dated: April 6, 2012.

David R. Shipman,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2012–8825 Filed 4–11–12; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R–1433]

RIN 7100–AD83

Reserve Requirements of Depository Institutions: Reserves Simplification

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending Regulation D, Reserve Requirements of Depository Institutions, to simplify the administration of reserve requirements. The final rule creates a common two-week maintenance period for all depository institutions, creates a penalty-free band around reserve balance requirements in place of carryover and routine penalty waivers, discontinues as-of adjustments related to deposit report revisions, replaces all other as-of adjustments with direct compensation, and eliminates the contractual clearing balance program. The amendments are designed to reduce the administrative and operational costs associated with reserve requirements for depository institutions, the Board, and Federal Reserve Banks.

DATES: *Effective Date:* This rule is effective on July 12, 2012, except that effective on January 24, 2013, the following sections are further amended: § 204.2(z), (ff), (gg) and (hh); § 204.5 (b)(2), (d)(4)(i), and (e); § 204.6 (a) and (b); § 204.10 (b)(1), (b)(3), and (c).

FOR FURTHER INFORMATION CONTACT: Kara Handzlik, Senior Attorney (202) 452–3852, Legal Division, or Margaret Gillis DeBoer, Assistant Director (202) 452–3139, or Heather Wiggins, Senior Financial Analyst (202) 452–3674, Division of Monetary Affairs, or for questions regarding the Private Sector Adjustment Factor, Gregory Evans, Deputy Associate Director (202) 452–3945, or Brenda Richards, Manager (202) 452–2753, Division of Reserve Bank Operations and Payment Systems; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869; Board of Governors of the

Federal Reserve System, 20th and C Streets NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Background

Section 19 of the Federal Reserve Act (Act) [1] authorizes the Board of Governors of the Federal Reserve System (Board) to impose reserve requirements on certain deposits and other liabilities of depository institutions for the purpose of implementing monetary policy. The Board's Regulation D (Reserve Requirements of Depository Institutions, 12 CFR part 204) implements section 19 of the Act and establishes reserve requirement ratios within the limits mandated by the Act. Under Regulation D currently, transaction account balances maintained at each depository institution are subject to reserve requirement ratios of zero, three, or ten percent, depending on the level of transaction accounts at that institution.[2] A depository institution satisfies its reserve requirement by its holdings of vault cash and, if vault cash is insufficient to meet the requirement, by maintaining balances in an account at a Federal Reserve Bank (Reserve Bank). An institution may maintain balances either in the institution's own account at a Reserve Bank or in a pass-through correspondent's Reserve Bank account. The amount of balances that an institution must maintain if its reserve requirement is not satisfied by vault cash is referred to as the institution's reserve balance requirement. An institution satisfies its reserve balance requirement on average over a specified period of time, referred to as a maintenance period.

Currently, an institution may also enter into an agreement with its Reserve Bank under which the institution agrees to maintain a specific minimum balance in its account (referred to as a contractual clearing balance). Contractual clearing balances generate earning credits that the institution can use to offset service charges it incurs through its use of Federal Reserve priced services. In addition, an institution may also maintain excess balances. Excess balances are balances maintained by an institution in its account at a Reserve Bank that are in excess of the balances maintained to satisfy its reserve balance requirement and the contractual clearing balance requirement (if any).

Congress amended the Act in 2008 to authorize the Reserve Banks to pay interest on balances of eligible institutions at a rate or rates determined by the Board and not to exceed the general level of short-term interest rates.[3] The Board amended Regulation D in 2008 to allow Reserve Banks to pay interest on balances maintained to satisfy reserve balance requirements and excess balances. Both types of balances currently earn interest at the rate of 25 basis points.[4] Contractual clearing balances generate earnings credits, as noted above, but they do not earn explicit interest payments.[5]

II. Request for Public Comment and Summary of Comments Received

On October 18, 2011, the Board requested public comment on proposed amendments to Regulation D and on several issues related to the methodology used to create the Private Sector Adjustment Factor (76 FR 64250 (Oct. 18, 2011)). One comment was received on the Private Sector Adjustment Factor; the comment will be addressed in a future **Federal Register** notice along with previous comments to the Board's proposal to replace the current ''correspondent bank model'' with a model based on publicly traded firms.[6]

The Board received 43 comments in response to its request for comment on the Regulation D amendments. The responses consisted of comments from 4 depository institutions, 19 employees of financial institutions, 12 financial institution trade associations, and 8 individuals. Thirteen commenters addressed the proposed amendments to Regulation D; 8 of these 13 commenters also addressed issues not raised by the proposal. Thirty commenters addressed only issues not raised by the proposal. All but one of the 13 commenters on the proposed Regulation D amendments generally supported the proposal, but suggested (sometimes conflicting) amendments, provided support contingent on certain conditions, or requested that the Board delay the implementation date(s) of one or more of the proposed amendments. These comments are discussed in more detail below.

The majority of comments on issues not raised by the proposal concerned limits on the number of certain convenient transfers that may be made each month from savings deposit accounts. The Board most recently addressed this issue in its May 2009 Regulation D rulemaking (72 FR 25629, 25631 (May 29, 2009)) when it finalized amendments to increase from three to six the permissible monthly number of transfers or withdrawals from savings deposits by check, debit card, or similar order payable to third parties. As noted in the May 2009 rulemaking, the Board must impose reserve requirements on transaction accounts and not on other types of accounts, such as savings deposits, pursuant to section 19 of the Federal Reserve Act.[7] The Board believes the current numeric limitation is necessary for the Board to maintain the ability to distinguish between reservable and non-reservable types of deposit accounts.

III. Analysis of Proposed Simplifications and Comments

The Board proposed amendments to Regulation D that would implement the following four simplifications related to the administration of reserve requirements:

1. Create a common two-week maintenance period for all depository institutions;
2. Create a penalty-free band around reserve balance requirements in place of using carryover and routine penalty waivers;
3. Discontinue as-of adjustments related to deposit report revisions and replace all other as-of adjustments with direct compensation; and
4. Eliminate the contractual clearing balance program.

The Board also proposed to make changes to various terms used throughout Regulation D in order to clarify the meaning, enhance the accuracy, and ensure the consistent application of those terms. These proposed changes included replacing the term ''required reserve balance'' with ''balances maintained to satisfy the reserve balance requirement,'' adding a definition of ''reserve balance requirement,'' and making conforming revisions throughout the regulation.

After consideration of the comments received, the Board is adopting the amendments to Regulation D substantially as proposed, with minor technical changes. The Board considers the final amendments to Regulation D appropriate given the current approach to implementing monetary policy. If the Federal Reserve changes its monetary policy framework, which includes the payment of interest on balances held

[1] 12 U.S.C. 461.

[2] 12 CFR 204.4(f) (reserve requirement ratios).

[3] Emergency Economic Stabilization Act of 2008, Public Law 110–343, § 128, 122 Stat. 3765 (2008).

[4] 12 CFR 204.10(b) (rates of interest paid on balances maintained by eligible institutions at Reserve Banks).

[5] Earnings credits currently are computed as 80 percent of the rolling 13-week average of the three-month Treasury bill rate.

[6] 74 FR 15481 (April 6, 2009).

[7] The Act requires the Board to impose reserve requirements in a ratio from zero to fourteen percent on reservable liabilities.

with Reserve Banks, the entire framework, including the provisions of Regulation D, would be reassessed. As a result of the Board's adoption of these final amendments to Regulation D, related Federal Reserve Bank operating circulars and manuals affected by the final amendments to Regulation D will be updated accordingly.

Create a Common Two-Week Maintenance Period for All Depository Institutions

As noted above, a depository institution satisfies its reserve balance requirement on average over a period of time that is known as a maintenance period. Currently, Regulation D provides for two types of maintenance periods: a one-week maintenance period and a two-week maintenance period. The determination of which maintenance period applies to an institution depends primarily on the frequency with which it is required to report its deposits to the Federal Reserve. The Board requires depository institutions to submit deposit reports at different frequencies depending on the amount of their reservable liabilities over the previous year. Depository institutions that have reservable liabilities above a certain amount (exemption amount) are required to submit deposit data either weekly or quarterly. Regulation D currently subjects weekly reporters to a two-week maintenance period and quarterly reporters to a one-week maintenance period. Institutions that have reservable liabilities below the exemption amount either submit deposit reports annually or are not required to report at all. Annual reporters and nonreporters with a contractual clearing balance are currently subject to a one-week maintenance period. Institutions that have neither reserve requirements nor clearing balance requirements receive interest payments at the excess balance rate because they do not maintain balances to satisfy reserve balance requirements.

From one year to another, some depository institutions switch reporting frequency because of changes in the levels of the institution's reservable liabilities. Specifically, some depository institutions may switch from a two-week maintenance period to a one-week maintenance period, or vice versa. In certain instances, depository institutions that become eligible to shift to a quarterly instead of weekly reporting frequency elect to remain at the higher reporting frequency in order to maintain the flexibility of satisfying reserve requirements over a two-week maintenance period instead of a one-week maintenance period.

The Board proposed to create a common two-week maintenance period for all depository institutions. Accordingly, the Board proposed to retain the two-week maintenance period requirement for weekly reporters in § 204.5(b)(1) of Regulation D, but to amend § 204.5(b)(2) to include quarterly reporters in the two-week maintenance period requirement. As set forth in the proposal, the common two-week maintenance period would tend to benefit depository institutions, Reserve Banks, and the Board by (1) providing greater flexibility to depository institutions that currently satisfy reserve balance requirements over a one-week maintenance period; (2) reducing unnecessary complexity in the existing maintenance period structure; (3) reducing administrative and operational costs for depository institutions that may otherwise have had to change maintenance periods when deposit reporting categories (and therefore length of maintenance period) changed; and (4) reducing the operational and administrative cost for Reserve Banks and the Board by eliminating business processes and controls associated with maintaining two maintenance periods.

The Board received 12 comments on the proposed common two-week maintenance period. Of these comments, 11 supported the creation of a common two-week maintenance period, and generally agreed that a common two-week maintenance period would reduce burden. One commenter expressed concern that annual reporters would face increased burden under the common two-week maintenance period if they were required to submit two weeks of data rather than a single day of data. The proposed common two-week maintenance period, however, does not change the frequency or the amount of data an institution must report, but rather changes the period of time over which an institution would satisfy its reserve balance requirement (if any). Annual reporters will continue to be required to report one day's worth of data, once a year, and have a reserve requirement of zero.

The Board is adopting the common two-week maintenance period as proposed. As noted in the proposal, for depository institutions that report their deposits weekly, the relationship between weekly reporting periods and two-week maintenance periods will be maintained in § 204.5(b)(1) of Regulation D. For depository institutions that report their deposits quarterly, the quarterly reporting periods will not change, but the relationship of quarterly reporting periods to two-week maintenance periods will be new. Revised § 204.5(b)(2) provides that, for quarterly reporters, each quarterly report will be used to calculate the reporter's reserve balance requirement for an interval of either six or seven consecutive two-week maintenance periods, depending on when the interval begins and ends. The interval will begin on the fourth Thursday following the end of each quarterly reporting period if that Thursday is the first day of a two-week maintenance period. If the fourth Thursday following the end of a quarterly reporting period is not the first day of a two-week maintenance period, then the interval will begin on the fifth Thursday following the end of the quarterly reporting period. The interval will end on the fourth Wednesday following the end of the subsequent quarterly reporting period if that Wednesday is the last day of a two-week maintenance period. If the fourth Wednesday following the end of the subsequent quarterly reporting period is not the last day of a two-week maintenance period, then the interval will conclude on the fifth Wednesday following the end of the subsequent quarterly reporting period.[8]

Annual reporters and nonreporters will continue to receive interest on their average balances maintained with Reserve Banks; however, the interest payments will be calculated on the average balance maintained over a two-week period at the excess balance rate instead of a one-week period at the excess balance rate.

Create a Penalty-Free Band Around Reserve Balance Requirements in Place of Carryover and Routine Penalty Waivers

As noted above, Regulation D requires a depository institution to satisfy its reserve balance requirement on average over that depository institution's maintenance period. Currently, § 204.5(e) of Regulation D permits a depository institution that has a modest deficiency in its balances maintained to satisfy a reserve balance requirement over a given maintenance period to make up that deficiency by holding a higher level of balances in the subsequent maintenance period. Correspondingly, § 204.5(e) also permits

[8] The Board currently provides quarterly reporters with reserve maintenance calendars that link quarterly reporting periods to a group of one-week maintenance periods. See *http://www.frbservices.org/centralbank/reservescentral/index.html#rmc.* The Board will update these reserve maintenance calendars to reflect the new rule.

a depository institution that has a modest excess of balances maintained to satisfy its reserve balance requirement over a maintenance period to use that excess by holding a lower level of balances in the next maintenance period. This ''carryover'' provision (the ability to carry an excess or deficiency from one maintenance period over to the next) essentially prevents a Reserve Bank from determining whether a depository institution has satisfied its reserve balance requirement, or is in an excess or deficient position, until the completion of the subsequent maintenance period. As a result, Reserve Banks must delay the payment of interest and assessment of deficiency charges on eligible institutions' balances. Section 204.6(a) currently authorizes Reserve Banks to assess deficiency charges against depository institutions that fail to satisfy their reserve balance requirements. Section 204.6(b) currently permits Reserve Banks to waive the imposition of these charges under certain conditions through the use of ''routine penalty waivers.''

The Board proposed to create a penalty-free band around each depository institution's reserve balance requirement and to eliminate the carryover and routine penalty waiver provisions of Regulation D. Specifically, proposed § 204.2(gg) defined the top of the penalty-free band as an amount equal to an institution's reserve balance requirement plus an amount that is the greater of 10 percent of the institution's reserve balance requirement or $50,000. Proposed § 204.2(hh) defined the bottom of the penalty-free band as an amount equal to an institution's reserve balance requirement less an amount that is the greater of 10 percent of an institution's reserve balance requirement or $50,000. For pass-through correspondents, the Board proposed setting the dollar amount used to establish the top and bottom of the penalty-free band at an amount that is equal to the greater of 10 percent of the aggregate reserve balance requirement of the correspondent (if any) and all of its respondents or $50,000.

Proposed § 204.2(z) revised the definition of ''excess balance'' to mean the average balance maintained in a Reserve Bank account by or on behalf of an institution over a reserve maintenance period that exceeds the top of the penalty-free band, and proposed § 204.2(ff) defined ''deficiency'' as the bottom of the penalty-free band less the average balance maintained in a Reserve Bank account by or on behalf of an institution over a reserve maintenance period. Under the proposed structure, a depository institution that maintained balances that exceeded the reserve balance requirement, but fell within the band, would be remunerated at the interest rate paid on balances maintained to satisfy a reserve balance requirement. Balances that exceeded the top of the penalty-free band would be remunerated at the interest rate paid on excess balances. A depository institution that maintained balances below its reserve balance requirement would not be assessed a deficiency charge unless the balances fell below the bottom of the penalty-free band. The Board also proposed to remove § 204.5(e) and amend §§ 204.6(a) and (b) to eliminate the application of carryover and routine penalty waivers, respectively. Reserve Banks would, however, retain the authority to waive charges for deficiencies based on an evaluation of the circumstances in each individual case. Finally, the Board proposed conforming amendments to § 204.10(b)(1) and (b)(3), and (c) to replace ''required reserve balances'' with ''balances up to the top of the penalty-free band.''

Six commenters generally supported the Board's proposal to create a penalty-free band around each depository institution's reserve balance requirement and to eliminate the carryover and routine waiver provisions of Regulation D. However, two of the commenters that supported this simplification requested different dollar amounts be used to establish the top and bottom of the penalty-free band. One commenter suggested a smaller dollar amount equal to the greater of $50,000 or 6 percent of a depository institution's reserve balance requirement. This commenter stated that institutions would be provided with sufficient flexibility if the band were defined in this manner. The other commenter requested the dollar amount be calculated similarly to the current carryover amount, using the greater of $50,000 or 4 percent of a depository institution's total reserve requirement (as opposed to 10 percent of its reserve balance requirement). This commenter was concerned that a band based on a reserve balance requirement may affect the Federal Reserve's ability to implement monetary policy in the event that all depository institutions' reserve balance requirements were zero.

The Board is adopting the penalty-free band as proposed, with one technical addition, and is eliminating the use of carryover and routine penalty waivers as proposed. The Board is clarifying that in no case will the bottom of the penalty-free band be less than zero. The Board believes that the proposed width of the penalty-free band will roughly replicate the amount of flexibility currently provided under the carryover provision. On average, reserve balance requirements are just under half of total reserve requirements. Therefore, the flexibility provided by the existing 4 percent carryover provision, when expressed in terms of reserve balance requirements, equates to roughly 10 percent of the reserve balance requirement for a typical depository institution. In addition, the Board believes a band constructed in terms of reserve balance requirements (rather than reserve requirements) is appropriate. Reserve balance requirements are more relevant than reserve requirements for implementing monetary policy and controlling the federal funds rate, because reserve balance requirements determine the amount of balances depository institutions are required to maintain in Reserve Bank accounts. The Board also acknowledges that the penalty-free band is applicable only in monetary policy frameworks where reserve balance requirements are non-zero. If in the future all reserve balance requirements were zero, which could result from either a significant change to the Federal Reserve's monetary policy framework or from depository institutions' limiting the amount of their reservable liabilities, the Board would reassess the penalty-free band and other aspects of the monetary policy framework accordingly.

The Board received four comments on the proposed elimination of the carryover provision. These commenters supported the elimination provided that interest is paid soon after a maintenance period ends on balances maintained to satisfy a reserve balance requirement and excess balances. The Board anticipates that the elimination of carryover will allow for faster crediting of interest payments.

Discontinue as-of Adjustments Related to Deposit Report Revisions and Replace All Other as-of Adjustments With Direct Compensation

As-of Adjustments for Deposit Report Revisions

Depository institutions are required to submit revisions to past deposit reports to correct for reporting errors. Currently, when those revisions result in a change in the depository institution's reserve balance requirement, an as-of adjustment is used to correct the depository institution's level of balances maintained. For example, if a reserve balance requirement for a given period is revised upwards, the as-of adjustment is used so that the depository institution must hold a greater level of balances in a future maintenance period in order to meet its reserve balance requirement.

The Board proposed to eliminate the use of as-of adjustments for deposit report revisions. The payment of interest on balances maintained to satisfy reserve balance requirements essentially eliminates the need for as-of adjustments for deposit report revisions, because the interest rate paid effectively removes the implicit tax imposed by reserve requirements. The Board received no comments opposing the elimination of as-of adjustments for deposit report revisions and is adopting this provision as proposed. The Board notes that revisions to deposit reports to correct for reporting errors will still be required, because these reports are used to calculate and publish the monetary aggregates.

All As-of Adjustments Other Than Those Related to Deposit Report Revisions

In addition to use for deposit report revisions, as-of adjustments are currently used for other purposes as well. These purposes include, but are not limited to, correcting transaction errors, recovering float, and penalizing an institution for a reserve deficiency in lieu of assessing monetary charges. An as-of adjustment for a transaction-based error corrects the average level of balances maintained by the depository institution to the level that would have resulted had the error not occurred. An as-of adjustment to recover float compensates the Reserve Bank for the float that is created by an institution's request to defer check and ACH charges for days in which the institution is closed. Finally, an as-of adjustment to penalize an institution for a reserve deficiency can be used instead of imposing an explicit monetary charge to the institution's Reserve Bank account.

The Board proposed replacing as-of adjustments for transaction-based errors with direct compensation (that is, either a debit or credit applied to an account to offset the effect of an error). The Board proposed replacing as-of adjustments for recovering float with explicit billing charges when float arises from temporary institution closings. Finally, the Board proposed eliminating the use of as-of adjustments for reserve deficiency penalties and relying solely on the assessment of explicit deficiency charges. The Board proposed to pay (or charge) an institution in these situations at a rate based on the federal funds rate.[9]

Three commenters supported the replacement of as-of adjustments with direct compensation for all as-of adjustments other than those related to deposit report revisions, provided that institutions may continue to obtain detailed information on the error that occurred and the calculation of the compensation amount. These commenters stated that such detailed information is needed to verify the error, to reconcile accounts, and to allocate charges (or payments) by correspondents to the appropriate respondents. Five commenters supported the use of the federal funds rate to compensate depository institutions for transaction-based errors. No alternative compensation rate was suggested.

The Board is adopting the final rule as proposed.[10] The Board anticipates that the Reserve Banks will make the appropriate information and documentation available to depository institutions as may be needed to permit institutions to reconcile accounts and allocate charges or payments. For example, information will be available that helps describe the calculation of direct compensation entries including the error amount, the start and end date of the error, and identification of the originating service area. The Board also anticipates that Reserves Banks will provide institutions with contact information for service areas processing direct compensation entries so that inquiries can be addressed.

Eliminate the Contractual Clearing Balance Program

As noted above, a depository institution may voluntarily agree with a Reserve Bank to maintain a level of balances in excess of the amount necessary to satisfy its reserve balance requirement. The actual amount that a depository institution maintains under such an agreement is known as a clearing balance.[11] Reserve Banks do not pay explicit interest on clearing balances. Instead, clearing balances generate earnings credits that a depository institution may then use to pay for Reserve Bank priced services.

The Board proposed to eliminate the contractual clearing balance program. The Board proposed to amend Regulation D to remove the definitions of ''clearing balance'' (§ 204.2(v)), ''clearing balance allowance'' (§ 204.2(w)), and ''contractual clearing balance'' (§ 204.2(x)), along with the removal of any other references to clearing balances and contractual clearing balances elsewhere in Regulation D.

Commenters generally supported the elimination of the contractual clearing balance program. However, one commenter stated that the elimination of the program may increase the possibility of overdrafts in depository institutions' Reserve Bank accounts if it was ever the case that the rate paid on balances held at Reserve Banks is below the federal funds rate and trading in the federal funds market is more active. This commenter suggested the Board announce its intent to continue the payment of interest on such balances at a rate equal to or greater than the federal funds rate.

The Board is adopting the elimination of the contractual clearing balance program as proposed. The elimination of the contractual clearing balance program will enhance the Federal Reserve's ability to carry out monetary policy by eliminating the complexities associated with maintaining different balance requirements for different kinds of balances and different kinds and levels of interest rates (explicit and implicit). The elimination of the contractual clearing balance program will not have any effect on a Reserve Bank's ability to require institutions to maintain a minimum level of balances in their Reserve Bank accounts in order for Reserve Banks to protect against overdrafts.[12] The Board established the rate of interest paid on balances maintained to satisfy reserve balance requirements at a level that implements monetary policy and that eliminates the implicit tax imposed by reserve requirements. The Board will continue to evaluate the appropriate level of interest rates to achieve these stated objectives and will communicate changes when necessary.

Effective Dates

The Board proposed to eliminate the contractual clearing balance program and the use of as-of adjustments no earlier than the first quarter of 2012, and to implement a common maintenance period and the penalty-free band around reserve balance requirements no earlier than the third quarter of 2012. Four commenters stated that the proposed effective date for the elimination of

[9] The federal funds rate is used in other instances of direct compensation by Reserve Banks. *See, e.g.,* § 210.32(b)(1)(ii) of Regulation J (federal funds rate applies if compensation interest rate not otherwise determined by agreement or rule).

[10] Consistent with these amendments to Regulation D, elsewhere in the **Federal Register** the Board is finalizing conforming changes to the provisions in Regulation J that refer to as-of adjustments.

[11] 12 CFR 204.2(v) (definition of clearing balance).

[12] *See* Reserve Bank Operating Circulars at *http://www.frbservices.org/regulations/operating_circulars.html.*

clearing balances and as-of adjustments was too aggressive in light of other regulatory changes, and suggested implementation of these simplifications no earlier than the beginning of the third quarter of 2012, 90 days after publication of the final rule, or a period of nine months. Four other commenters requested that the implementation of all simplifications be delayed for either a period of nine months or at least until the first quarter of 2013. Additionally, a subset of these commenters requested that the Board provide for a staggered implementation of the simplifications.

The Board will eliminate the contractual clearing balance program and the use of as-of adjustments earlier than it will implement the common maintenance period and the penalty-free band. Given that commenters generally noted that few operational changes would be necessary to prepare for the proposed amendments, the Board will eliminate the contractual clearing balance program on July 12, 2012. Also on this date, as-of adjustments will no longer be created and issuance of direct compensation will begin. This date is approximately 90 days after the publication of the final rule and is within the time period suggested by some commenters as appropriate to prepare for the amendments. The Board will implement the common two-week maintenance period, the penalty-free band, and the elimination of carryover and routine penalty waivers on January 24, 2013. The Board will provide public notice no later than November 1, 2012, if the January 24, 2013 date will be delayed.

IV. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (the ''RFA'') (5 U.S.C. 601 *et seq.*) requires agencies either to provide a final regulatory flexibility analysis with a final rule or to certify that the rule will not have a significant economic impact on a substantial number of small entities. In accordance with the RFA, the Board reviewed the final rule, which would apply to all depository institutions. Based on current information, the Board believes that, although a significant number of ''small banking organizations'' will be affected by the rule, the rule will not have a significant economic impact on these small entities because the Board expects the amendments to decrease costs for all institutions, including smaller institutions. The Board prepared an initial regulatory flexibility analysis in accordance with 5 U.S.C. 603 of the RFA in its notice of proposed rulemaking and sought comment on the potential impact of the proposed rule on small entities. The Board did not receive any comments on the initial regulatory flexibility analysis.

1. *Statement of the need for, objectives of, and legal basis for, the final rule.* The Board proposed to amend Regulation D to simplify the administration of reserve requirements. Section 19 of the Federal Reserve Act requires the Board to impose reserve requirements on certain deposits and other liabilities of depository institutions solely for the purposes of implementing monetary policy. The Board's Regulation D implements section 19 of the Act. The Board believes that the amendments to Regulation D will reduce the administrative and operational costs associated with reserve requirements for depository institutions.

2. *Summary of significant issues raised by public comment on the Board's initial analysis of issues, and a statement of any changes made as a result.* The Board did not receive any public comments on the proposed rule addressing matters relating to the Board's initial regulatory flexibility analysis.

3. *Small entities affected by the final rule.* The final rule applies to all depository institutions. Pursuant to regulations issued by the Small Business Administration (the ''SBA'') (13 CFR 121.201), a ''small banking organization'' includes a depository institution with $175 million or less in total assets. Based on data reported as of December 31, 2011, the Board believes that there are approximately 10,313 small depository institutions. Out of these small depository institutions, the Board believes that small institutions affected by the final rule include approximately 3,181 small depository institutions that maintain balances to satisfy reserve balance requirements over a one-week maintenance period; approximately 1,775 small depository institutions with contractual clearing balances; and approximately 197 small depository institutions that received at least one as-of adjustment in 2011.

4. *Recordkeeping, reporting, and other compliance requirements.* Although the final rule imposes certain compliance requirements on depository institutions, the Board believes that the overall effect of the final rule on depository institutions, including small depository institutions, will be positive. Under new § 204.5(b)(2), small depository institutions that satisfy their reserve balance requirement on a one-week maintenance period (approximately 3,181) will be subject to a two-week maintenance period. A depository institution may choose, however, not to change its internal systems accordingly, because it could continue to satisfy its requirement weekly within the two-week maintenance period. The final rule will also eliminate the contractual clearing balance program, currently used by approximately 1,775 small depository institutions. Although the contractual clearing program will be eliminated, the Board does not anticipate that small depository institutions will be negatively affected because small depository institutions will receive explicit interest payments on excess balances instead of earnings credits on clearing balances. Small depository institutions can then use this explicit interest to pay for Reserve Bank priced services or for other purposes, providing them with increased flexibility. In addition, the final rule eliminates the use of as-of adjustments for deposit revisions. The Board does not believe the elimination of as-of adjustments for deposit revisions will negatively affect small depository institutions because the interest rate paid on balances maintained to satisfy a reserve balance requirement effectively removes the implicit tax imposed by reserve requirements.

5. *Identification of duplicative, overlapping, or conflicting Federal rules.* The Board has not identified any Federal rules that duplicate, overlap, or conflict with the final rule. In a separate rulemaking, the Board is finalizing amendments to Regulation J to remove references to as-of adjustments in order to conform that regulation to this rule.

6. *Significant alternatives to the proposed rule.* The Board designed the reserve simplifications to reduce administrative and operational burdens on depository institutions. Commenters did not suggest any alternatives to the final rule that accomplish that objective.

V. Paperwork Reduction Act Analysis

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget (OMB). Although the mandatory data collected on the deposits reporting forms [13] are used by the Federal Reserve for administering Regulation D and for constructing, analyzing, and monitoring

[13] Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900; OMB No. 7100–0087), Annual Report of Total Deposits and Reservable Liabilities (FR 2910a; OMB No. 7100–0175), Report of Foreign (Non-U.S.) Currency Deposits (FR 2915; OMB No. 7100–0237), and Allocation of Low Reserve Tranche and Reservable Liabilities Exemption (FR 2930; OMB No. 7100–0088).

the monetary and reserve aggregates, none of the revisions in this rulemaking change the deposits reporting forms. The rule contains no collections of information under the PRA. *See* 44 U.S.C. 3502(3). Accordingly, no paperwork burden is associated with the rule. The Board received no comments on this analysis.

List of Subjects in 12 CFR Part 204

Banks, banking, Federal Reserve System, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Board is amending 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 461, 601, 611, and 3105.

■ 2. Effective July 12, 2012, § 204.1 paragraph (b) is revised to read as follows:

§ 204.1 Authority, purpose and scope.

* * * * *

(b) *Purpose.* This part relates to reserve requirements imposed on depository institutions for the purpose of facilitating the implementation of monetary policy by the Federal Reserve System.

* * * * *

■ 3. Effective July 12, 2012, § 204.2 is amended by:

■ A. Removing and reserving paragraphs (v) through (x);

■ B. Revising paragraphs (z) and (bb); and

■ C. Adding paragraphs (ee) and (ff).

The additions and revisions read as follows:

§ 204.2 Definitions.

* * * * *

(z) *Excess balance* means the average balance maintained in an account at a Federal Reserve Bank by or on behalf of an institution over a reserve maintenance period that exceeds the balance maintained to satisfy a reserve balance requirement.

* * * * *

(bb) *Balance maintained to satisfy a reserve balance requirement* means the average balance held in an account at a Federal Reserve Bank by or on behalf of an institution over a reserve maintenance period to satisfy a reserve balance requirement of this part.

* * * * *

(ee) *Reserve balance requirement* means the balance that a depository institution is required to maintain on average over a reserve maintenance period in an account at a Federal Reserve Bank if vault cash does not fully satisfy the depository institution's reserve requirement imposed by this part.

(ff) *Deficiency* means the reserve balance requirement less the average balance maintained in an account at a Federal Reserve Bank by or on behalf of an institution over a reserve maintenance period.

* * * * *

■ 4. Effective January 24, 2013, § 204.2 is further amended by:

■ A. Revising paragraphs (z) and (ff); and

■ B. Adding paragraphs (gg) and (hh).

The additions and revisions read as follows:

§ 204.2 Definitions.

* * * * *

(z) *Excess balance* means the average balance maintained in an account at a Federal Reserve Bank by or on behalf of an institution over a reserve maintenance period that exceeds the top of the penalty-free band.

* * * * *

(ff) *Deficiency* means the bottom of the penalty-free band less the average balance maintained in an account at a Federal Reserve Bank by or on behalf of an institution over a reserve maintenance period.

(gg) *Top of the penalty-free band* means an amount equal to an institution's reserve balance requirement plus an amount that is the greater of 10 percent of the institution's reserve balance requirement or $50,000. The top of the penalty-free band for a pass-through correspondent is an amount equal to the aggregate reserve balance requirement of the correspondent (if any) and all of its respondents plus an amount that is the greater of 10 percent of that aggregate reserve balance requirement or $50,000.

(hh) *Bottom of the penalty-free band* means an amount equal to an institution's reserve balance requirement less an amount that is the greater of 10 percent of the institution's reserve balance requirement or $50,000. The bottom of the penalty-free band for a pass-through correspondent is an amount equal to the aggregate reserve balance requirement of the correspondent (if any) and all of its respondents less an amount that is the greater of 10 percent of that aggregate reserve balance requirement or $50,000. In no case will the penalty-free band be less than zero.

■ 5. Effective July 12, 2012, in § 204.4 revise paragraphs (d) and (e), and the introductory text of paragraph (f), to read as follows:

§ 204.4 Computation of required reserves.

* * * * *

(d) For institutions that file a report of deposits weekly, reserve requirements are computed on the basis of the institution's daily average balances of deposits and Eurocurrency liabilities during a 14-day computation period ending every second Monday.

(e) For institutions that file a report of deposits quarterly, reserve requirements are computed on the basis of the institution's daily average balances of deposits and Eurocurrency liabilities during the 7-day computation period that begins on the third Tuesday of March, June, September, and December.

(f) For all depository institutions, Edge and Agreement corporations, and United States branches and agencies of foreign banks, reserve requirements are computed by applying the reserve requirement ratios below to net transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities of the institution during the computation period.

* * * * *

■ 6. Effective July 12, 2012, § 204.5 is amended by revising paragraphs (a)(1), (b), (c), (d), and (e) to read as follows:

§ 204.5 Maintenance of required reserves.

(a)(1) A depository institution, a U.S. branch or agency of a foreign bank, and an Edge or Agreement corporation shall satisfy reserve requirements by maintaining vault cash and, if vault cash does not fully satisfy the institution's reserve requirement, in the form of a balance maintained

(i) In the institution's account at the Federal Reserve Bank in the Federal Reserve District in which the institution is located, or

(ii) With a pass-through correspondent in accordance with § 204.5(d).

* * * * *

(b)(1) For institutions that file a report of deposits weekly, the balances maintained to satisfy reserve balance requirements shall be maintained during a 14-day maintenance period that begins on the third Thursday following the end of a given computation period.

(2) For institutions that file a report of deposits quarterly, the balances maintained to satisfy reserve balance requirements shall be maintained during each of the 7-day maintenance periods during the interval that begins on the fourth Thursday following the end of the institution's computation

period and ends on the fourth Wednesday after the close of the institution's next computation period.

(c) Cash items forwarded to a Federal Reserve Bank for collection and credit are not included in an institution's balance maintained to satisfy its reserve balance requirement until the expiration of the time specified in the appropriate time schedule established under Regulation J, ''Collection of Checks and Other Items by Federal Reserve Banks and Funds Transfers Through Fedwire'' (12 CFR part 210). If a depository institution draws against items before that time, the charge will be made to its account if the balance is sufficient to pay it; any resulting deficiency in balances maintained to satisfy the institution's reserve balance requirement will be subject to the penalties provided by law and to the deficiency charges provided by this part. However, the Federal Reserve Bank may, at its discretion, refuse to permit the withdrawal or other use of credit given in an account for any time for which the Federal Reserve Bank has not received payment in actually and finally collected funds.

(d)(1) A depository institution, a U.S. branch or agency of a foreign bank, or an Edge or Agreement corporation with a reserve balance requirement (''respondent'') may select only one pass-through correspondent under this section, unless otherwise permitted by the Federal Reserve Bank in whose District the respondent is located. Eligible pass-through correspondents are Federal Home Loan Banks, the National Credit Union Administration Central Liquidity Facility, and depository institutions, U.S. branches or agencies of foreign banks, and Edge and Agreement corporations that maintain balances to satisfy their own reserve balance requirements which may be zero, in an account at a Federal Reserve Bank. In addition, the Board reserves the right to permit other institutions, on a case-by-case basis, to serve as pass-through correspondents.

(2) Respondents or correspondents may institute, terminate, or change pass-through correspondent agreements by providing all documentation required for the establishment of the new agreement or termination of or change to the existing agreement to the Federal Reserve Banks involved within the time period specified by those Reserve Banks.

(3) Balances maintained to satisfy reserve balance requirements of a correspondent's respondents shall be maintained along with the balances maintained to satisfy a correspondent's reserve balance requirement (if any), in a single commingled account of the correspondent at the Federal Reserve Bank in whose District the correspondent is located. Balances maintained in the correspondent's account are the property of the correspondent and represent a liability of the Reserve Bank solely to the correspondent, regardless of whether the funds represent the balances maintained to satisfy the reserve balance requirement of a respondent.

(4)(i) A pass-through correspondent shall be responsible for maintaining balances to satisfy its own reserve balance requirement (if any) and the reserve balance requirements of all of its respondents. A Federal Reserve Bank will compare the total reserve balance requirement to be satisfied by the correspondent with the total balance maintained to satisfy a reserve balance requirement by the correspondent for purposes of determining deficiencies, imposing or waiving charges for deficiencies and for other reserve maintenance purposes. A charge for a deficiency in the correspondent's account will be imposed by the Reserve Bank on the correspondent maintaining the account.

(ii) Each correspondent is required to maintain detailed records for each of its respondents that permit Reserve Banks to determine whether the respondent has provided a sufficient funds to the correspondent to satisfy the reserve balance requirement of the respondent. The correspondent shall maintain such records and make such reports as the Board or Reserve Bank may requires in order to ensure the correspondent's compliance with its responsibilities under this section and shall make them available to the Board or Reserve Bank as required.

(iii) The Federal Reserve Bank may terminate any pass-through agreement under which the correspondent is deficient in its recordkeeping or other responsibilities.

(iv) Interest paid on supplemental reserves (if such reserves are required under § 204.7) held by a respondent will be credited to the account maintained by the correspondent.

(e) Any excess or deficiency in an institution's balance maintained to satisfy its reserve balance requirement shall be carried over and applied against the balance maintained in the next maintenance period as specified in this paragraph. The amount of any such excess or deficiency that is carried over shall not exceed the greater of:

(1) The amount obtained by multiplying 0.04 times the depository institution's reserve requirement; or

(2) $50,000. Any carryover not offset during the next period may not be carried over to subsequent periods.

■ 7. Effective January 24, 2013, § 204.5 is further amended by:

■ A. Revising paragraphs (b)(2) and (d)(4)(i); and

■ B. Removing paragraph (e).

The additions and revisions read as follows:

§ 204.5 Maintenance of required reserves.

* * * * *

(b) * * *

(2) For institutions that file a report of deposits quarterly, the balances maintained to satisfy reserve balance requirements shall be maintained during an interval of either six or seven consecutive 14-day maintenance periods, depending on when the interval begins and ends. The interval will begin on the fourth Thursday following the end of each quarterly reporting period if that Thursday is the first day of a 14-day maintenance period. If the fourth Thursday following the end of a quarterly reporting period is not the first day of a 14-day maintenance period, then the interval will begin on the fifth Thursday following the end of the quarterly reporting period. The interval will end on the fourth Wednesday following the end of the subsequent quarterly reporting period if that Wednesday is the last day of a 14-day maintenance period. If the fourth Wednesday following the end of the subsequent quarterly reporting period is not the last day of a 14-day maintenance period, then the interval will conclude on the fifth Wednesday following the end of the subsequent quarterly reporting period.

* * * * *

(d) * * *

(4)(i) A pass-through correspondent shall be responsible for maintaining balances to satisfy its own reserve balance requirement (if any) and the reserve balance requirements of all of its respondents. A charge for any deficiency in the correspondent's account will be imposed by the Reserve Bank on the correspondent maintaining the account.

* * * * *

■ 8. Effective July 12, 2012, § 204.6 is amended by revising the section heading and paragraphs (a) and (b), to read as follows:

§ 204.6 Charges for deficiencies.

(a) Deficiencies in a depository institution's balance maintained to satisfy its reserve balance requirement after application of the carryover provided in § 204.5(e), are subject to deficiency charges. Federal Reserve Banks are authorized to assess charges for deficiencies at a rate of 1 percentage point per year above the primary credit rate, as provided in § 201.51(a) of this chapter, in effect for borrowings from the Federal Reserve Bank on the first day of the calendar month in which the deficiencies occurred. Charges shall be assessed on the basis of daily average deficiencies during each maintenance period.

(b) Reserve Banks may waive the charges for deficiencies except when the deficiency arises out of a depository institution's gross negligence or conduct that is inconsistent with the principles and purposes of reserve requirements. Decisions by Reserve Banks to waive charges are based on an evaluation of the circumstances in each individual case and the depository institution's reserve maintenance record. For example, a waiver may be appropriate for a small charge or once during a two-year period for a deficiency that does not exceed a certain percentage of the depository institution's reserve requirement. If a depository institution has demonstrated a lack of due regard for the proper maintenance of balances to satisfy its reserve balance requirement, the Reserve Bank may decline to exercise the waiver privilege and assess all charges regardless of amount or reason for the deficiency.

* * * * *

■ 9. Effective January 24, 2013, § 204.6 is further amended by revising paragraphs (a) and (b) to read as follows:

§ 204.6 Charges for deficiencies.

(a) Federal Reserve Banks are authorized to assess charges for deficiencies at a rate of 1 percentage point per year above the primary credit rate, as provided in § 201.51(a) of this chapter, in effect for borrowings from the Federal Reserve Bank on the first day of the calendar month in which the deficiencies occurred. Charges shall be assessed on the basis of daily average deficiencies during each maintenance period.

(b) Reserve Banks may waive the charges for deficiencies based on an evaluation of the circumstances in each individual case.

* * * * *

■ 10. Effective July 12, 2012, § 204.10 is amended by revising paragraphs (b)(1), (b)(3), (c), (d)(3) and (e)(2) to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

(b) * * *

(1) For balances maintained to satisfy reserve balance requirements, at ¼ percent;

* * * * *

(3) For balances maintained to satisfy reserve balance requirements, excess balances, and term deposits, at any other rate or rates as determined by the Board from time to time, not to exceed the general level of short-term interest rates. For purposes of this paragraph (b), ''short-term interest rates'' are rates on obligations with maturities of no more than one year, such as the primary credit rate and rates on term federal funds, term repurchase agreements, commercial paper, term Eurodollar deposits, and other similar instruments.

(c) *Pass-through balances.* A pass-through correspondent that is an eligible institution may pass back to its respondent interest paid on balances maintained to satisfy a reserve balance requirement of that respondent. In the case of balances maintained by a pass-through correspondent that is not an eligible institution, a Reserve Bank shall pay interest only on the balances maintained to satisfy a reserve balance requirement of one or more respondents, and the correspondent shall pass back to its respondents interest paid on balances in the correspondent's account.

(d) * * *

(3) Balances maintained in an excess balance account will not satisfy any institution's reserve balance requirement.

* * * * *

(e) * * *

(2) A term deposit will not satisfy any institution's reserve balance requirement.

* * * * *

■ 11. Effective January 24, 2013, § 204.10 is further amended by revising paragraphs (b)(1), (b)(3), and (c) to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

(b) * * *

(1) For balances up to the top of the penalty-free band, at ¼ percent;

* * * * *

(3) For balances up to the top of the penalty-free band, excess balances, and term deposits, at any other rate or rates as determined by the Board from time to time, not to exceed the general level of short-term interest rates. For purposes of this subsection, ''short-term interest rates'' are rates on obligations with maturities of no more than one year, such as the primary credit rate and rates on term federal funds, term repurchase agreements, commercial paper, term Eurodollar deposits, and other similar instruments.

(c) *Pass-through balances.* A pass-through correspondent that is an eligible institution may pass back to its respondent interest paid on balances maintained to satisfy a reserve balance requirement of that respondent. In the case of balances maintained by a pass-through correspondent that is not an eligible institution, a Reserve Bank shall pay interest only on the balances maintained to satisfy a reserve balance requirement of one or more respondents up to the top of the penalty-free band, and the correspondent shall pass back to its respondents interest paid on balances in the correspondent's account.

* * * * *

By order of the Board of Governors of the Federal Reserve System, April 5, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–8562 Filed 4–11–12; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 210

[Regulation J; Docket No. R–1434]

RIN 7100 AD 84

Collection of Checks and Other Items by Federal Reserve Banks and Funds Transfers Through Fedwire: Elimination of ''As-of Adjustments'' and Other Clarifications

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending Regulation J (Collection of Checks and Other Items by Federal Reserve Banks and Funds Transfers through Fedwire). The final rule eliminates references to ''as-of adjustments'' consistent with the Board's final amendments to Regulation D to simplify reserves administration; clarifies that an institution's Administrative Reserve Bank is deemed to have accepted deposit of a check or other item even if the institution sends the item directly to another Federal Reserve Bank; further clarifies that Regulation J continues to apply to a Fedwire funds transfer even if the funds transfer also meets the definition of ''remittance transfer'' under the Electronic Fund Transfer Act; and makes other conforming revisions.

DATES: This final rule is effective July 12, 2012.

FOR FURTHER INFORMATION CONTACT: Kara Handzlik, Senior Attorney (202) 452–

3852, Legal Division; Margaret Gillis DeBoer, Assistant Director (202) 452–3139, or Heather Wiggins, Senior Financial Analyst (202) 452–3674, Division of Monetary Affairs; or Joseph Baressi, Project Leader, Division of Reserve Bank Operations and Payment Systems (202) 452–3959; for users of Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869; Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Background

Subpart A of Regulation J governs the collection of checks and other items by the Federal Reserve Banks (Reserve Banks), including the types of checks or other items that may be sent to Reserve Banks, the order in which they are deemed to be handled, and the related warranties and indemnities. Subpart B of Regulation J sets forth the terms and conditions under which Reserve Banks receive and deliver payment orders from and to depository institutions over the Reserve Banks' Fedwire® Funds Service (Fedwire).

On October 18, 2011, the Board proposed amendments to Regulation J, including the elimination of references throughout Regulation J to a Reserve Bank's use of ''as-of adjustments'' (76 FR 64259). The Board proposed these amendments, in part, to conform to proposed amendments to Regulation D (12 CFR part 204) to simplify reserves administration.[1] The Board also proposed amendments to subpart A of Regulation J to clarify where a check or other item is deemed to be accepted when it is sent to a Reserve Bank. Specifically, the proposal clarified that when an institution sends a check or other item for collection to a Reserve Bank, the institution's Administrative Reserve Bank is deemed to have accepted deposit of the item even if the item was sent directly to another Reserve Bank. In addition, the Board proposed amendments to clarify that subpart B of Regulation J continues to apply to a Fedwire funds transfer even if that funds transfer also meets the definition of ''remittance transfer'' under the recently revised Electronic Fund Transfer Act (''EFTA''). After consideration of the comments received, the Board is adopting the amendments to Regulation J as proposed.

II. Request for Public Comment and Summary of Comments Received

The Board requested public comment on its October 2011 proposal to amend Regulation J. The Board received a total of eight comments from six financial institution trade associations, one depository institution, and one association of depository institutions. Commenters generally expressed support for the proposed amendments, although some were concerned with various aspects of the proposal and provided support contingent on certain conditions. These comments are discussed in more detail below.

III. Analysis of Proposed Simplifications and Comments

Eliminate References to As-of Adjustments

Regulation J defines ''as-of adjustment'' for purposes of subpart B of the regulation as ''a debit or credit, for reserve- or clearing-balance maintenance purposes only, applied to the reserve or clearing balance of a bank that either sends a payment order to a Federal Reserve Bank, or that receives a payment order from a Federal Reserve Bank, in lieu of an interest charge or payment.''[2] Regulation J currently permits a Reserve Bank to use either an as-of adjustment or direct compensation (at the federal funds rate) to compensate for an error in transaction processing or other damages owed in connection with a Fedwire funds transfer. Regulation J further provides in subpart A that a Reserve Bank's operating circulars may include procedures for paying interest in the form of as-of adjustments in relation to the collection of checks and other items.

As noted above, the Board proposed to amend Regulation D to simplify the rules governing the administration of reserve requirements. The proposed Regulation D amendments included discontinuing as-of adjustments related to deposit report revisions and replacing all other as-of adjustments with direct compensation in the form of either a debit or credit applied to an account to offset the effect of an error. Consistent with its Regulation D proposal, the Board proposed to amend Regulation J §§ 210.3(a), 210.26(b), and 210.32(b) (along with the corresponding commentary) to eliminate references to as-of adjustments. Under the Board's Regulation J proposal, a Reserve Bank would continue to be able to pay direct compensation to a depository institution based on the federal funds rate in accordance with § 210.32(b), which incorporates by reference section 4A–506 of article 4A of the Uniform Commercial Code (UCC).[3] The Board specifically requested comment on the following two items: whether use of the federal funds rate for the calculation of direct compensation is appropriate, and if not, the rate that the Board should use, and whether the Board should eliminate § 210.32(b)(1) of Regulation J entirely, as the Reserve Banks could simply pay direct compensation based on the provisions of UCC section 4A–506, which is already incorporated into Regulation J.

The Board received eight comments concerning the elimination of references to as-of adjustments. Commenters generally supported this amendment. One commenter requested that the debit or credit entry post directly to the account bearing the routing number of the original transaction and that the supporting documentation be forwarded directly to the depository institution holding that account. Two commenters conditioned their support of this change on Reserve Banks continuing to provide depository institutions with information on the error that occurred and the calculation of the compensation amount. With respect to compensation at the federal funds rate, one commenter stated that the federal funds rate should be used while another commenter stated that the rate for calculating the compensation amount should be at least equal to the federal funds rate. With respect to the elimination of § 210.32(b)(1), one commenter recommended that the Board eliminate this section entirely and allow the Reserve Banks to pay direct compensation based on the provisions of UCC section 4A–506, which is already incorporated into Regulation J.

The Board is adopting §§ 210.3(a), 210.26(b), and 210.32(b) as proposed (along with the corresponding commentary). These final amendments correspond to the Board's adoption of final amendments to Regulation D to discontinue as-of adjustments related to deposit report revisions and to replace all other as-of adjustments with direct compensation. Under the final rules, the federal funds rate will be used for the calculation of direct compensation. The Board believes that the federal funds rate is the appropriate rate for direct compensation in order to ensure that a

---

[1] The proposed amendments to Regulation D were published in the **Federal Register** on October 18, 2011 (76 FR 64250). The Board proposed to discontinue the use of as-of adjustments for deposit report revisions and to replace all other as-of adjustments with direct compensation, create a common two-week maintenance period for all depository institutions, create a penalty-free band around reserve balance requirements in place of carryover and routine waivers, and eliminate the contractual clearing balance program.

[2] 12 CFR 210.26(b).

[3] Article 4A–506(b) states that if the amount of interest is not determined by an agreement or rule, the applicable federal funds rate would apply.

depository institution does not gain or lose in its position as a result of accounting or administrative errors or delays in transaction processing by Reserve Banks. The Board believes it is prudent to retain § 210.32(b)(1) to give appropriate context to the subsequent provision, § 210.32(b)(2), which concerns the pass-through of compensation to the appropriate party. Under § 210.32(b)(2), an institution that receives a compensation payment but is not the party entitled to compensation would continue to be required to pass the benefit of that payment through to the party entitled to compensation, computed as the value of the payment as if it had been passed through to the entitled party on the day the Reserve Bank effected payment to the institution. The Board anticipates that the Reserve Banks will make the appropriate information and documentation available to depository institutions as may be needed to permit institutions to reconcile accounts and allocate charges or payments. For example, information will be available that helps describe the calculation of direct compensation entries including the error amount, the start and end date of the error, and identification of the originating service area. The Board also anticipates that Reserve Banks will provide institutions with contact information for service areas processing direct compensation entries so that inquiries can be addressed.

Acceptance of Deposits of Items

Section 210.4 of Regulation J governs the sending and handling of checks and other items sent to Reserve Banks. The Reserve Banks have long permitted institutions to send checks to a Reserve Bank other than the institution's Administrative Reserve Bank. These ''direct sends'' facilitate a more efficient check-collection process. Section 210.4 currently specifies the identity and order of the parties that are deemed to handle a check or other item, whether it is deposited electronically or in paper form, that is sent to a Reserve Bank for purposes of determining the rights and liabilities of the parties under Regulation J, Regulation CC (12 CFR part 229), and the UCC. Specifically, § 210.4 provides that, for an item sent to a Reserve Bank for collection, the following parties are deemed to have handled the item in the following order: (1) The initial sender; (2) the initial sender's Administrative Reserve Bank; [4] (3) the Reserve Bank that receives the item from the initial sender (if different from the initial sender's Administrative Reserve Bank); and (4) another Reserve Bank, if any, that receives the item from a Reserve Bank.

The Board proposed to amend § 210.4(b)(1)(ii) to clarify that, when an Administrative Reserve Bank is deemed to have ''handled'' a check sent directly to another Reserve Bank, such ''handling'' of an item includes accepting the item for deposit. Thus, for purposes of determining the rights and liabilities of parties that send and handle checks and other items sent to a Reserve Bank, the Administrative Reserve Bank is deemed to have accepted deposit of the item from the initial sender even if the sender sends the item directly to another Reserve Bank. The Board further proposed to clarify in § 210.4(b)(3) that, in addition to Regulation J, Regulation CC, and the UCC, the identity and order of the parties in § 210.4(b) also determines the relationships and the rights and liabilities of the parties for purposes of sections 13(1) and 16(13) of the Federal Reserve Act, which govern deposits to Reserve Banks.[5]

The Board received six comments supporting this clarification and no comments opposing the clarification. The Board is adopting this clarification as proposed.

Application of Regulation J to ''Remittance Transfers''

As noted above, Fedwire funds transfers are governed by subpart B of Regulation J. More specifically, subpart B of Regulation J currently ''governs a funds transfer that is sent through Fedwire * * * even though a portion of the funds transfer is governed by the Electronic Fund Transfer Act [EFTA], but the portion of such funds transfer that is governed by the [EFTA] is not governed by'' Regulation J.[6] This provision is slightly different from (and supersedes) the scope of UCC Article 4A–108, which provides that Article 4A does not apply ''to a funds transfer, any part of which is governed by the [EFTA].'' Prior to the adoption of the recently enacted Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the exclusion from Regulation J and Article 4A of transactions governed by the EFTA did not create any gaps or overlap because the EFTA excluded from the definition of ''electronic fund transfer'' wire transfers over systems that are not designed primarily for consumer transfers (such as Fedwire).[7] The Dodd-Frank Act, however, added new section 919 to the EFTA, which defines ''remittance transfer'' to include an electronic transfer of funds requested by a U.S. consumer sender through a remittance transfer provider, whether or not the remittance transfer is also an electronic fund transfer as defined in the EFTA. Therefore, a Fedwire funds transfer could potentially be part of a remittance transfer under the new section 919 of the EFTA.[8] Consequently, under Regulation J's current scope provision (§ 210.25(b)(3)), Fedwire funds transfers that meet the EFTA's definition of ''remittance transfer'' could be viewed as ''governed by'' the EFTA and therefore not governed by Regulation J.

To avoid a gap in coverage for Fedwire funds transfers, the Board proposed to amend § 210.25 of Regulation J to clarify that Regulation J continues to apply to ''remittance transfers'' as defined by the EFTA, to the extent there is not an inconsistency between Regulation J and section 919 of the EFTA (in which case section 919 would prevail). The proposed clarification was intended to ensure that the provisions of Regulation J, and therefore Article 4A of the UCC, apply to all Fedwire funds transfers, except to the extent that section 919 of the EFTA and rules established thereunder apply. The proposal included clarifications in the commentary to § 210.25 as well.

Commenters generally supported this clarification; however, three commenters requested that the Board coordinate with the Consumer Financial Protection Bureau (CFPB) before finalizing this rule due to outstanding issues regarding the ''remittance transfer'' final rule. Another commenter supported the proposal but pointed out that although this amendment will clarify the application of Regulation J for Fedwire transactions, the clarification will not apply to non-Fedwire wire transfers governed by Article 4A.

The Board is adopting the clarification to Regulation J as proposed. At the time the Board published the related proposal for this rulemaking, the CFPB had yet to finalize amendments to Regulation E to implement section 919 of the EFTA. The CFPB has since finalized this rulemaking.[9] The CFPB's final rule includes a discussion on the

[4] An institution's Administrative Reserve Bank is the Reserve Bank in whose District the institution is located. 12 CFR 210.2(c), *see* section 204.3(g) of Regulation D, 12 CFR 204.3(g) (location of depository institutions).

[5] 12 U.S.C. 342 and 360.

[6] 12 CFR 210.25(b)(3).

[7] 15 U.S.C. 1693a(6)(B).

[8] See the Consumer Financial Protection Bureau's final amendments to Regulation E (12 CFR part 1005) to implement section 919 of the EFTA (77 FR 6194 (Feb. 7, 2012)).

[9] 77 FR 6194 (February 7, 2012).

relationship between the EFTA and Article 4A of the UCC.[10]

Conforming Revisions

The Board is making non-substantive changes in §§ 210.2, 210.10, and 210.11 to conform terminology to the final amendments in Regulation D concerning the use of various reserve-related terms. Regulation J § 210.2(a) currently defines the term ''account'' as an account with reserve or clearing balances on the books of a Federal Reserve Bank. Consistent with the Regulation D final rulemaking, the Board is amending § 210.2(a) to refer simply to balances on the books of a Federal Reserve Bank. In addition, Regulation J §§ 210.10 and 210.11, which concern the availability of credit to depository institutions, currently refer to ''reserve.'' Section 210.11(a), for example, states that a Reserve Bank shall provide credit of a noncash item when it receives payment in actually and finally collected funds and that the amount of such noncash item ''is counted as reserve for purposes'' of Regulation D. Consistent with the final amendments to Regulation D, the Board is amending §§ 210.10(a) and 210.11(a), (b), and (c) by replacing the term ''reserve'' with ''balance maintained to satisfy a reserve balance requirement.''

Effective Date

The Board proposed that the effective date for the elimination of references to as-of adjustments be the same as the effective date of the corresponding amendments to Regulation D (no earlier than the first quarter of 2012). The Board proposed an effective date of 30 days after adoption of the final rule for the other clarifications. The Board received three comments concerning the proposed effective dates. Two of these commenters requested that the effective date of the changes be staggered, with a delayed effective date for the first change of at least nine months. One of these commenters stated that the elimination of references to ''as-of adjustments'' be made in conjunction with the changes in Regulation D and made effective no earlier than the first quarter of 2013. This commenter also recommended that the two clarifications be made effective no earlier than the first quarter of 2013 because banks have already established their change management plans for 2012 and the clarifications will require additional changes to policies and procedures.

The Board is setting the effective date for the elimination of ''as-of adjustments'' and changes to reserve terminology as July 12, 2012. This is the same effective date as that which has been finalized for the corresponding amendments to Regulation D. The Board is setting the effective date for the other two clarifications also as July 12, 2012. Given that these amendments will not require institutions to take any action or incur any cost, the Board believes this date is appropriate.

IV. Competitive Impact Analysis

As a matter of policy, the Board subjects all operational and legal changes that could have a substantial effect on payment system participants to a competitive impact analysis.[11] Pursuant to this policy, the Board assesses whether proposed changes ''would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services due to differing legal powers or constraints or because of a dominant market position of the Federal Reserve deriving from such legal differences.'' If as a result of this analysis the Board identifies an adverse effect on the ability to compete, the Board then assesses whether the associated benefits—such as improvements to payment system efficiency or integrity—can be achieved while minimizing the adverse effect on competition.

The final amendments that eliminate the use of as-of adjustments require Reserve Banks to pay compensation in the form of explicit interest under UCC Article 4A–506, as is required of private sector service providers. The final amendments to section 210.4, clarifying the status of the Administrative Reserve Bank of a sender of a check, does not affect the competitive position of the Reserve Banks vis-à-vis private-sector service providers. With respect to the final amendments to section 210.25 (clarifying the applicability of Regulation J to remittance transfers as defined in the Electronic Fund Transfer Act), private-sector funds transfer systems may have the ability to adopt clearing-house rules that will vary the Uniform Commercial Code, although the extent to which this variation may occur remains unclear. Nevertheless, the Board does not believe this difference in certainty with respect to a small subset of funds transfers will have a material adverse effect on the ability of other service providers to compete with the Reserve Banks. Therefore, as noted in the proposal, the Board does not believe the amendments to Regulation J will have any direct and material adverse effect on the ability of other service providers to compete with the Reserve Banks.

V. Final Regulatory Flexibility Analysis

Congress enacted the Regulatory Flexibility Act (the ''RFA'') (5 U.S.C. 601 *et seq.*) to address concerns related to the effects of agency rules on small entities and the Board is sensitive to the impact its rules may impose on small entities. The RFA requires agencies either to provide an initial regulatory flexibility analysis with a proposed rule or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. In accordance with section 3(a) of the RFA, the Board reviewed the proposed regulation. In this case, the rule applies to all depository institutions. Based on current information, the Board believes that the rule would not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)). Nonetheless, the Board prepared an Initial Regulatory Flexibility Analysis in accordance with 5 U.S.C. 603 in order for the Board to solicit comment on the potential impact of the proposed rule on small entities. The Board received no comments on its request.

1. *Statement of the need for, objectives of, and legal basis for, the final rule.* The final amendments to Regulation J eliminate references to ''as-of adjustments'' consistent with the Board's amendments to Regulation D (12 CFR part 204), which simplify reserves administration. The amendments also clarify that an institution's Administrative Reserve Bank is deemed to have accepted deposit of a check or other item even if the institution sends the item directly to another Federal Reserve Bank. The amendments further clarify that Regulation J continues to apply to a Fedwire funds transfer even if the funds transfer also meets the definition of ''remittance transfer'' under the Electronic Fund Transfer Act. The amendments also make conforming changes to terminology.

2. *Summary of significant issues raised by public comment on the Board's initial analysis of issues, and a statement of any changes made as a result.* The Board did not receive any public comments on the proposed rule addressing matters relating to the Board's initial regulatory flexibility analysis.

3. *Small entities affected by the final rule.* The rule affects all institutions that

[10] *Id.* at 6211–6212.

[11] *See* ''The Federal Reserve in the Payments System,'' Fed. Res. Reg. Svc. ¶¶ 9–1550, 9–1558 (Apr. 2009).

use Federal Reserve Bank check or wire transfer services. Pursuant to regulations issued by the Small Business Administration (the ''SBA'') (13 CFR 121.201), a ''small banking organization'' includes a depository institution with $175 million or less in total assets. Based on data reported as of December 31, 2011, the Board believes that there are approximately 10,313 small depository institutions, approximately 2,754 of which have a master account with a Federal Reserve Bank.

4. *Record keeping, reporting, and other compliance requirements.* The final rule eliminates references to as-of adjustments and replaces the use of as-of adjustments with direct compensation based on the federal funds rate. As noted above, a depository institution should not be harmed by this amendment because the depository institution will continue to be compensated for the income effects of a transaction error; the payment will simply be in the form of direct compensation instead of an as-of adjustment. The other amendments to Regulation J are clarifications and do not impose new requirements on depository institutions.

5. *Identification of duplicative, overlapping, or conflicting Federal rules.* The Board has not identified any Federal rules that duplicate, overlap, or conflict with the rule. The Board's final clarification to § 210.25 that relates to Article 4A of the UCC actually avoids a potential conflict that might arise by operation of the EFTA and Regulation E.

6. *Significant alternatives to the proposed rule.* The Board is unaware of any significant alternatives to the rule that accomplish the stated objectives of the Board. Commenters did not suggest any alternatives that would minimize the impact of the rule on small entities.

VI. Paperwork Reduction Act Analysis

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget (OMB). No collections of information pursuant to the PRA are contained in the final rule. The Board received no comments on this analysis.

List of Subjects in 12 CFR Part 210

Banks, banking, Federal Reserve System.

Authority and Issuance

For the reasons set forth in the preamble, the Board is amending Regulation J, 12 CFR part 210, as follows:

PART 210—COLLECTION OF CHECKS AND OTHER ITEMS BY FEDERAL RESERVE BANKS AND FUNDS TRANSFERS THROUGH FEDWIRE (REGULATION J)

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 12 U.S.C. 248(i), (j), and (o), 342, 360, 464, 4001–4010, and 5001–5018.

■ 2. In § 210.2, paragraph (a) is revised to read as follows:

§ 210.2 Definitions.

* * * * *

(a) *Account* means an account on the books of a Federal Reserve Bank. A subaccount is an informational record of a subset of transactions that affect an account and is not a separate account.

* * * * *

■ 3. In § 210.3, paragraph (a) is revised to read as follows:

§ 210.3 General provisions.

(a) *General.* Each Reserve Bank shall receive and handle items in accordance with this subpart, and shall issue operating circulars governing the details of its handling of items and other matters deemed appropriate by the Reserve Bank. The circulars may, among other things, classify cash items and noncash items, require separate sorts and letters, provide different closing times for the receipt of different classes or types of items, provide for instructions by an administrative Reserve Bank to other Reserve Banks, set forth terms of services, and establish procedures for adjustments on a Reserve Bank's books, including amounts, waiver of expenses, and payment of compensation.

* * * * *

■ 4. Section 210.4 is revised to read as follows:

§ 210.4 Sending items to Reserve Banks.

(a) *Sending of items.* A sender, other than a Reserve Bank, may send any item to any Reserve Bank, whether or not the item is payable within the Reserve Bank's District, unless the sender's administrative Reserve Bank directs the sender to send the item to a specific Reserve Bank.

(b) *Handling of items.* (1) The following parties, in the following order, are deemed to have handled an item that is sent to a Reserve Bank for collection:

(i) The initial sender;

(ii) The initial sender's administrative Reserve Bank (which is deemed to have accepted deposit of the item from the initial sender);

(iii) The Reserve Bank that receives the item from the initial sender (if different from the initial sender's administrative Reserve Bank); and

(iv) Another Reserve Bank, if any, that receives the item from a Reserve Bank.

(2) A Reserve Bank that is not described in paragraph (b)(1) of this section is not a person that handles an item and is not a collecting bank with respect to an item.

(3) The identity and order of the parties under paragraph (b)(1) of this section determine the relationships and the rights and liabilities of the parties under this subpart, part 229 of this chapter (Regulation CC), section 13(1) and section 16(13) of the Federal Reserve Act, and the Uniform Commercial Code. An initial sender's administrative Reserve Bank that is deemed to accept an item for deposit or handle an item is also deemed to be a sender with respect to that item. The Reserve Banks that are deemed to handle an item are deemed to be agents or subagents of the owner of the item, as provided in section 210.6(a) of this subpart.

(c) *Checks received at par.* The Reserve Banks shall receive cash items and other checks at par.

■ 5. In § 210.10, paragraph (a) is revised to read as follows:

§ 210.10 Time schedule and availability of credits for cash items and returned checks.

(a) Each Reserve Bank shall include in its operating circulars a time schedule for each of its offices indicating when the amount of any cash item or returned check received by it is counted toward the balance maintained to satisfy a reserve balance requirement for purposes of part 204 of this chapter (Regulation D) and becomes available for use by the sender or paying or returning bank. The Reserve Bank that holds the settlement account shall give either immediate or deferred credit to a sender, a paying bank, or a returning bank (other than a foreign correspondent) in accordance with the time schedule of the receiving Reserve Bank. A Reserve Bank ordinarily gives credit to a foreign correspondent only when the Reserve Bank receives payment of the item in actually and finally collected funds, but, in its discretion, a Reserve Bank may give immediate or deferred credit in accordance with its time schedule.

* * * * *

■ 6. Section 210.11 is revised to read as follows:

§ 210.11 Availability of proceeds of noncash items; time schedule.

(a) *Availability of credit.* A Reserve Bank shall give credit to the sender for the proceeds of a noncash item when it receives payment in actually and finally collected funds (or advice from another Reserve Bank of such payment to it). The amount of the item is counted toward the balance maintained to satisfy a reserve balance requirement for purposes of part 204 of this chapter (Regulation D) and becomes available for use by the sender when the Reserve Bank receives the payment or advice, except as provided in paragraph (b) of this section.

(b) *Time schedule.* A Reserve Bank may give credit for the proceeds of a noncash item subject to payment in actually and finally collected funds in accordance with a time schedule included in its operating circulars. The time schedule shall indicate when the proceeds of the noncash item will be counted toward the balance maintained to satisfy a reserve balance requirement for purposes of part 204 of this chapter (Regulation D) and become available for use by the sender. A Reserve Bank may, however, refuse at any time to permit the use of credit given by it for a noncash item for which the Reserve Bank has not yet received payment in actually and finally collected funds.

(c) *Handling of payment.* If a Reserve Bank receives, in payment for a noncash item, a bank draft of other form of payment that it elects to handle as a noncash item, the Reserve Bank shall neither count the proceeds toward the balance maintained to satisfy a reserve balance requirement for purposes of part 204 of this chapter (Regulation D) nor make the proceeds available for use until it receives payment in actually and finally collected funds.

■ 7. In § 210.25, paragraphs (b)(1) and (b)(3) are revised to read as follows:

§ 210.25 Authority, purpose, and scope.

* * * * *

(b) * * *

(1) This subpart incorporates the provisions of article 4A set forth in appendix B to this subpart. In the event of an inconsistency between the provisions of the sections of this subpart and appendix B to this subpart, the provisions of the sections of this subpart shall prevail. In the event of an inconsistency between the provisions this subpart and section 919 of the Electronic Fund Transfer Act, section 919 of the Electronic Fund Transfer Act shall prevail.

* * * * *

(3) This subpart governs a funds transfer that is sent through Fedwire, as provided in paragraph (b)(2) of this section, even though a portion of the funds transfer is governed by the Electronic Fund Transfer Act, but the portion of such funds transfer that is governed by the Electronic Fund Transfer Act (other than section 919 governing remittance transfers) is not governed by this subpart.

* * * * *

■ 8. In § 210.26, paragraph (b) is removed and reserved.

■ 9. In § 210.32, paragraphs (b)(1) and (b)(2) are revised to read as follows:

§ 210.32 Federal Reserve Bank liability; payment of interest.

* * * * *

(b) * * *

(1) A Federal Reserve Bank shall satisfy its obligation, or that of another Federal Reserve Bank, to pay compensation in the form of interest under article 4A by paying compensation in the form of interest to its sender, its receiving bank, its beneficiary, or another party to the funds transfer that is entitled to such payment, in an amount that is calculated in accordance with section 4A–506 of article 4A.

(2) If the sender or receiving bank that is the recipient of interest payment is not the party entitled to compensation under article 4A, the sender or receiving bank shall pass through the benefit of the interest payment by making an interest payment, as of the day the interest payment is effected, to the party entitled to compensation. The interest payment that is made to the party entitled to compensation shall not be less than the value of the interest payment that was provided by the Federal Reserve Bank to the sender or receiving bank. The party entitled to compensation may agree to accept compensation in a form other than a direct interest payment, provided that such an alternative form of compensation is not less than the value of the interest payment that otherwise would be made.

* * * * *

■ 10. In appendix A to subpart B:

■ a. In Section 210.25, paragraph (b) is revised.

■ b. In Section 210.26, paragraph (i) is revised.

■ c. In Section 210.32, paragraph (b) is revised.

The revisions read as follows:

Appendix A to Subpart B of Part 210—Commentary

* * * * *

Section 210.25—Authority, Purpose, and Scope

* * * * *

(b) *Scope.* (1) Subpart B of this part incorporates the provisions of article 4A set forth in appendix B of this part. The provisions set forth expressly in the sections of subpart B of this part supersede or preempt any inconsistent provisions of article 4A as set forth in appendix B of this part or as enacted in any state. The official comments to article 4A are not incorporated in subpart B of this part or this commentary to subpart B of this part, but the official comments may be useful in interpreting article 4A. Because section 4A–105 refers to other provisions of the Uniform Commercial Code, e.g., definitions in article 1 of the UCC, these other provisions of the UCC, as approved by the National Conference of Commissioners on Uniform State Laws and the American Law Institute, from time to time, are also incorporated in subpart B of this part. Subpart B of this part applies to any party to a Fedwire funds transfer that is in privity with a Federal Reserve Bank. These parties include a sender (bank or nonbank) that sends a payment order directly to a Federal Reserve Bank, a receiving bank that receives a payment order directly from a Federal Reserve Bank, and a beneficiary that receives credit to an account that it uses or maintains at a Federal Reserve Bank for a payment order sent to a Federal Reserve Bank. Other parties to a funds transfer are covered by this subpart to the same extent that this subpart would apply to them if this subpart were a ''funds-transfer system rule'' under article 4A that selected subpart B of this part as the governing law.

(2) The scope of the applicability of a funds-transfer system rule under article 4A is specified in section 4A–501(b), and the scope of the choice of law provision is specified in section 4A–507(c). Under section 4A–507(c), a choice of law provision is binding on the participants in a funds-transfer system and certain other parties having notice that the funds-transfer system might be used for the funds transfer and of the choice of law provision. The Uniform Commercial Code provides that a person has notice when the person has actual knowledge, receives notification, or has reason to know from all the facts and circumstances known to the person at the time in question. (See UCC § 1–201(25).) However, under sections 4A–507(b) and 4A–507(d), a choice of law by agreement of the parties takes precedence over a choice of law made by funds-transfer system rule.

(3) If originators, receiving banks, and beneficiaries that are not in privity with a Federal Reserve Bank have the notice contemplated by Section 4A–507(c) or if those parties agree to be bound by subpart B of this part, subpart B of this part generally would apply to payment orders between those remote parties, including participants in other funds-transfer systems. For example, a funds transfer may be sent from an originator's bank through a funds-transfer system other than Fedwire to a receiving bank which, in turn, sends a payment order through Fedwire to execute the funds transfer. Similarly, a Federal Reserve Bank may execute a payment order through

Fedwire to a receiving bank that sends it through a funds-transfer system other than Fedwire to a beneficiary's bank. In the first example, if the originator's bank has notice that Fedwire may be used to effect part of the funds transfer, the sending of the payment order through the other funds-transfer system to the receiving bank will be governed by subpart B of this part unless the parties to the payment order have agreed otherwise. In the second example, if the beneficiary's bank has notice that Fedwire may be used to effect part of the funds transfer, the sending of the payment order to the beneficiary's bank through the other funds-transfer system will be governed by subpart B of this part unless the parties have agreed otherwise. In both cases, the other funds-transfer system's rules would also apply to, at a minimum, the portion of these funds transfers going through that funds transfer system. Because subpart B of this part is federal law, to the extent of any inconsistency, subpart B of this part will take precedence over any funds-transfer system rule applicable to the remote sender or receiving bank or to a Federal Reserve Bank. If remote parties to a funds transfer, a portion of which is sent through Fedwire, have expressly selected by agreement a law other than subpart B of this part under section 4A–507(b), subpart B of this part would not take precedence over the choice of law made by the agreement even though the remote parties had notice that Fedwire may be used and of the governing law. (See 4A–507(d).) In addition, subpart B of this part would not apply to a funds transfer sent through another funds-transfer system where no Federal Reserve Bank handles the funds transfer, even though settlement for the funds transfer is made by means of a separate net settlement or funds transfer through Fedwire.

(4) Under section 4A–108, article 4A does not apply to a funds transfer, any part of which is governed by the Electronic Fund Transfer Act (EFTA) (15 U.S.C. 1693 *et seq.*). In general, Fedwire funds transfers to or from consumer accounts are exempt from the EFTA and Regulation E (12 CFR part 205). A funds transfer from a consumer originator or a funds transfer to a consumer beneficiary could be carried out in part through Fedwire and in part through an automated clearinghouse or other means that is subject to the EFTA or Regulation E. In these cases, subpart B would not govern the portion of the funds transfer that is governed by the EFTA or Regulation E. (See the commentary to section 210.26(i) in this appendix, ''Payment Order''.)

(5) Section 919 of the EFTA, however, governs ''remittance transfers,'' which may include Fedwire funds transfers. Section 919 of the EFTA sets out the obligations of remittance transfer providers with respect to consumer senders of remittance transfers. Section 919 of the EFTA generally does not affect the rights and obligations of financial institutions involved in a remittance transfer. To the extent that a Fedwire funds transfer is a ''remittance transfer'' governed by section 919 of the EFTA, it continues to be governed by subpart B, except that, in the event of an inconsistency between the provisions of subpart B and section 919 of the EFTA, section 919 of the EFTA shall prevail. For example, a consumer may initiate a remittance transfer governed by EFTA section 919 from the consumer's account at a depository institution, and the depository institution may initiate that transfer by sending a payment order to a Reserve Bank through the Fedwire funds system. If the consumer subsequently exercised the right to cancel the remittance transfer and obtain a refund under the terms of EFTA section 919, the depository institution would be required to comply with section 919 even if the institution does not have a right to reverse the payment order sent to the Reserve Bank under subpart B.

(6) Finally, section 4A–404(a) provides that a beneficiary's bank is obliged to pay the amount of a payment order to the beneficiary on the payment date unless acceptance of the payment order occurs on the payment date after the close of the funds-transfer business day of the bank. The Expedited Funds Availability Act provides that funds received by a bank by wire transfer shall be available for withdrawal not later than the banking day after the business day on which such funds are received (12 U.S.C. 4002(a)). That act also preempts any provision of state law that was not effective on September 1, 1989, that is inconsistent with that act or its implementing Regulation CC (12 CFR 229). Accordingly, the Expedited Funds Availability Act and Regulation CC may preempt section 4A–404(a) as enacted in any state. In order to ensure that section 4A–404(a), or other provisions of article 4A, as incorporated in subpart B of this part, do not take precedence over provisions of the Expedited Funds Availability Act, this section provides that where subpart B of this part establishes rights or obligations that are also governed by the Expedited Funds Availability Act or Regulation CC, the Expedited Funds Availability Act or Regulation CC provision shall apply and subpart B of this part shall not apply.

* * * * *

Section 210.26—Definitions

* * * * *

(i) *Payment Order.* (1) The definition of ''payment order'' in subpart B of this part differs from the section 4A–103(a)(1) definition. The subpart B definition clarifies that, for the purposes of subpart B of this part, automated clearinghouse transfers and certain messages that are transmitted through Fedwire are not payment orders. Federal Reserve Banks and banks participating in Fedwire send various types of messages relating to payment orders or to other matters, through Fedwire, that are not intended to be payment orders. Under the subpart B definition, these messages, and messages involved with automated clearinghouse transfers, are not ''payment orders'' and therefore are not governed by this subpart. The operating circulars of the Federal Reserve Banks specify those messages that may be transmitted through Fedwire but that are not payment orders.

(2) In some cases, messages sent through Fedwire, such as certain requests for credit transfer, may be payment orders under article 4A, but are not treated as payment orders under subpart B because they are not an instruction to a Federal Reserve Bank to pay money.

(3) This subpart and article 4A govern a payment order even though the originator's or beneficiary's account may be a consumer account established primarily for personal, family, or household purposes. Under section 4A–108, article 4A does not apply to a funds transfer any part of which is governed by the Electronic Fund Transfer Act. That act, and Regulation E (12 CFR part 205) implementing it, do not apply to funds transfers through Fedwire (see 15 U.S.C. 1693a(6)(B) and 12 CFR 205.3(b)), except that section 919 of the Electronic Fund Transfer Act may govern a Fedwire funds transfer that is a ''remittance transfer.'' Such remittance transfers that are Fedwire funds transfers continue to be governed by this subpart. Thus, this subpart applies to all funds transfers through Fedwire even though some such transfers involve originators or beneficiaries that are consumers. (See also § 210.25(b) and accompanying commentary.)

* * * * *

Section 210.32—Federal Reserve Bank Liability; Payment of Interest

* * * * *

(b) *Payment of interest.* (1) Under article 4A, a Federal Reserve Bank may be required to pay compensation in the form of interest to another party in connection with its handling of a funds transfer. For example, payment of compensation in the form of interest is required in certain situations pursuant to sections 4A–204 (relating to refund of payment and duty of customer to report with respect to unauthorized payment order), 4A–209 (relating to acceptance of payment order), 4A–210 (relating to rejection of payment order), 4A–304 (relating to duty of sender to report erroneously executed payment order), 4A–305 (relating to liability for late or improper execution or failure to execute a payment order), 4A–402 (relating to obligation of sender to pay receiving bank), and 4A–404 (relating to obligation of beneficiary's bank to pay and give notice to beneficiary). Under section 4A–506(a), the amount of such interest may be determined by agreement between the sender and receiving bank or by funds-transfer system rule. If there is no such agreement, under section 4A–506(b), the amount of interest is based on the federal funds rate. Section 210.32(b) requires Federal Reserve Banks to provide compensation through an explicit interest payment.

(2) Interest would be calculated in accordance with the procedures specified in section 4A–506(b). Similarly, compensation in the form of explicit interest will be paid to government senders, receiving banks, or beneficiaries described in § 210.25(d) if they are entitled to interest under this subpart. A Federal Reserve Bank may also, in its discretion, pay explicit interest directly to a remote party to a Fedwire funds transfer that is entitled to interest, rather than providing compensation to its direct sender or receiving bank.

(3) If a bank that received an explicit interest payment is not the party entitled to interest compensation under article 4A, the bank must pass the benefit of the explicit

interest payment made to it to the party that is entitled to compensation in the form of interest from a Federal Reserve Bank. The benefit may be passed on either in the form of a direct payment of interest or in the form of a compensating balance, if the party entitled to interest agrees to accept the other form of compensation, and the value of the compensating balance is at least equivalent to the value of the explicit interest that otherwise would have been provided.

* * * * *

By order of the Board of Governors of the Federal Reserve System, April 5, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–8563 Filed 4–11–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2012–0352; Special Conditions No. 25–462–SC]

Special Conditions: Boeing, Model 777F; Enhanced Flight Vision System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Boeing Model 777F airplane. This airplane, as modified by the FedEx Express Corporation, will have a novel or unusual design feature associated with an advanced, enhanced flight vision system (EFVS). The EFVS consists of a head-up display (HUD) system modified to display forward-looking infrared (FLIR) imagery. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is March 22, 2012. We must receive your comments by May 14, 2012.

ADDRESSES: Send comments identified by docket number FAA–2012–0352 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 8 a.m. and 5 p.m., Monday through Friday, except federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Dale Dunford, FAA, Transport Standards Staff, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2239; fax 425–227–1320; email: *dale.dunford@faa.gov.*

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public-comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On November 17, 2010, the FedEx Express Corporation applied for a supplemental type certificate for the installation and operation of a HUD and an EFVS in the Boeing Model 777F. The original type certificate for the 777F airplanes is T00001SE, Revision 28, dated August 5, 2011.

The Boeing Model 777F is a transport-category, cargo-carrying airplane that operates with a crew of two. It is powered by two General Electric GE90–110B1 or GE90–115B turbofan engines, has a maximum gross takeoff weight of 766,800 pounds, and a maximum range of 4,900 nautical miles.

The electronic infrared image displayed between the pilot and the forward windshield represents a novel or unusual design feature in the context of Title 14, Code of Federal Regulations (14 CFR) 25.773. Section 25.773 was not written in anticipation of such technology. The electronic image has the potential to enhance the pilot's awareness of the terrain, hazards, and airport features. At the same time, the image may partially obscure the pilot's direct outside compartment view. Therefore, the FAA needs adequate safety standards to evaluate the EFVS to determine that the imagery provides the intended visual enhancements without undue interference with the pilot's outside compartment view. The FAA's intent is that the pilot will be able to use a combination of the information seen in the image and the natural view of the outside scene, as seen through the image, as safely and effectively as a pilot compartment view without an enhanced vision system (EVS) image, and is compliant with § 25.773.

Although the FAA has determined that the existing regulations are not adequate for certification of EFVSs, it believes that EFVSs could be certified through application of appropriate safety criteria. Therefore, the FAA has determined that special conditions should be issued for certification of EFVSs to provide a level of safety equivalent to that provided by the standard in § 25.773.

Note: The term ''enhanced vision system'' (EVS) in this document refers to a system comprised of a head-up display (HUD), imaging sensor(s), and avionics interfaces that display the sensor imagery on the HUD, and overlay that imagery with alpha-numeric and symbolic flight information. However, the term has also been commonly used in reference to systems that display the sensor imagery, with or without other flight information, on a head-down display. For clarity, the FAA created the term ''enhanced flight vision system'' (EFVS) to refer to certain EVS systems that meet the requirements of the new operational rules—in particular, the requirement for a HUD and specified flight information—and which can be used to determine ''enhanced flight visibility.'' An EFVS can be considered a subset of a system otherwise labeled EVS.

On January 9, 2004, the FAA published revisions to operational rules in 14 CFR parts 1, 91, 121, 125, and 135 to allow aircraft to operate below certain altitudes during a straight-in instrument approach while using an EFVS to meet visibility requirements.

Prior to this rule change, the FAA issued Special Conditions No. 25–180–SC, which applied to an EVS installed on Gulfstream Model G–V airplanes. Those special conditions addressed the requirements for the pilot compartment view and limited the scope of the intended functions permissible under the operational rules at the time. The intended function of the EVS imagery was to aid the pilot during the approach and allow the pilot to detect and identify the visual references for the intended runway down to 100 feet above the touchdown zone. However, the EVS imagery alone was not to be used as a means to satisfy visibility requirements below 100 feet.

The recent operational rule change expands the permissible application of certain EVSs that are certified to meet the new EFVS standards. The new rule allows the use of an EFVS for operation below the minimum descent altitude or decision height to meet new visibility requirements of § 91.175(l). The purpose of these special conditions is not only to address the issue of the ''pilot compartment view,'' as was done by Special Conditions No. 25–180–SC, but also to define the scope of intended function consistent with § 91.175(l) and (m).

Type Certification Basis

Under the provisions of 14 CFR 21.101, the FedEx Express Corporation must show that the Boeing Model 777F, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. T00001SE or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.'' The regulations incorporated by reference are listed in Type Certificate Data Sheet No. T00001SE, Revision 28, dated August 5, 2011, which covers all variants of the Boeing 777 airplanes. In addition, the certification basis includes certain special conditions and exemptions that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Boeing Model 777F because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model.

In addition to the applicable airworthiness regulations and special conditions, the Model 777F must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19 in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Boeing Model 777F will incorporate the following novel or unusual design feature: An EFVS that projects a video image derived from a FLIR camera through the HUD. The EFVS image is projected in the center of the ''pilot compartment view,'' which is governed by § 25.773. The image is displayed with HUD symbology and overlays the forward outside view. Therefore, § 25.773 does not contain appropriate safety standards for the EFVS display.

Operationally, during an instrument approach, the EFVS image is intended to enhance the pilot's ability to detect and identify ''visual references for the intended runway'' [see § 91.175(l)(3)] to continue the approach below decision height or minimum descent altitude. Depending on atmospheric conditions and the strength of infrared energy emitted and/or reflected from the scene, the pilot can see these visual references in the image better than they can be seen through the window without EFVS.

Scene contrast detected by infrared sensors can be much different from that detected by natural pilot vision. On a dark night, thermal differences of objects which are not detectable by the unaided eye are easily detected by many imaging infrared systems. On the other hand, contrasting colors in visual wavelengths may be distinguished by the naked eye but not by an imaging infrared system. Where thermal contrast in the scene is sufficiently detectable, the pilot can recognize shapes and patterns of certain visual references in the infrared image. However, depending on conditions, those shapes and patterns in the infrared image can appear significantly different than they would with normal vision. Considering these factors, the EFVS image needs to be evaluated to determine that it can be accurately interpreted by the pilot.

The EFVS image may improve the pilot's ability to detect and identify items of interest. However, the EFVS needs to be evaluated to determine that the imagery allows the pilot to perform the normal flightcrew duties and adequately see outside the window through the image, consistent with the safety intent of § 25.773(a)(2).

Compared to a HUD displaying the EFVS image and symbology, a HUD that only displays stroke-written symbols is easier to see through. Stroke symbology illuminates a small fraction of the total display area of the HUD, leaving much of that area free of reflected light that could interfere with the pilot's view out the window through the display. However, unlike stroke symbology, the video image illuminates most of the total display area of the HUD (approximately 30 degrees horizontally and 25 degrees vertically), which is a significant fraction of the pilot compartment view. The pilot cannot see around the larger illuminated portions of the video image, but must see the outside scene through it.

Unlike the pilot's external view, the EFVS image is a monochrome, two-dimensional display. Many, but not all, of the depth cues found in the natural view are also found in the image. The quality of the EFVS image and the level of EFVS infrared-sensor performance could depend significantly on conditions of the atmospheric and external light sources. The pilot needs adequate control of sensor gain and image brightness, which can significantly affect image quality and transparency (i.e., the ability to see the outside view through the image). Certain system characteristics could create distracting and confusing display artifacts. Finally, because this is a sensor-based system intended to provide a conformal perspective corresponding with the outside scene, the system must be able to ensure accurate alignment. Therefore, safety standards are needed for each of the following factors:

- An acceptable degree of image transparency;
- Image alignment;
- Lack of significant distortion; and
- The potential for pilot confusion or misleading information.

Section 25.773, Pilot compartment view, specifies that ''Each pilot compartment must be free of glare and reflection that could interfere with the normal duties of the minimum flight crew * * *.'' In issuing § 25.773, the FAA did not anticipate the development of the EFVS and does not consider that § 25.773 adequately addresses the specific issues related to such a system. Therefore, the FAA has determined that special conditions are needed to address the specific issues particular to the installation and use of an EFVS.

Discussion

The EFVS is intended to present an enhanced view during the landing approach. This enhanced view would help the pilot see and recognize external visual references, as required by § 91.175(l), and to visually monitor the integrity of the approach, as described in FAA Order 6750.24D, ''Instrument Landing System and Ancillary Electronic Component Configuration and Performance Requirements,'' dated March 1, 2000.

Based on this approved functionality, users would seek to obtain operational approval to conduct approaches, including approaches to Type I runways, in visibility conditions much lower than those for conventional Category I.

The purpose of these special conditions is to ensure that the EFVS to be installed can perform the following functions:

- Present an enhanced view that aids the pilot during the approach.
- Provide enhanced flight visibility to the pilot that is no less than the visibility prescribed in the standard instrument approach procedure.
- Display an image that the pilot can use to detect and identify the ''visual references for the intended runway'' required by 14 CFR 91.175(l)(3) to continue the approach with vertical guidance to 100 feet height above the touchdown-zone elevation.

Depending on the atmospheric conditions and the particular visual references that happen to be distinctly visible and detectable in the EFVS image, these functions would support its use by the pilot to visually monitor the integrity of the approach path.

Compliance with these special conditions does not affect the applicability of any of the requirements of the operating regulations (i.e., 14 CFR parts 91, 121, and 135). Furthermore, use of the EFVS does not change the approach minima prescribed in the standard instrument approach procedure being used; published minima still apply.

The FAA certification of this EFVS is limited as follows:

1. The infrared-based EFVS image will not be certified as a means to satisfy the requirements for descent below 100 feet height above touchdown.

2. The EFVS may be used as a supplemental device to enhance the pilot's situational awareness during any phase of flight or operation in which its safe use has been established.

An EFVS image may provide an enhanced image of the scene that may compensate for any reduction in the clear outside view of the visual field framed by the HUD combiner. The pilot must be able to use this combination of information seen in the image and the natural view of the outside scene, as seen through the image, as safely and effectively as the pilot would use a pilot compartment view without an EVS image that is compliant with § 25.773. This is the fundamental objective of the special conditions.

The FAA will also apply additional certification criteria, not as special conditions, for compliance with related regulatory requirements, such as §§ 25.1301 and 25.1309. These additional criteria address certain image characteristics, installation, demonstration, and system safety. Image-characteristics criteria include the following:

- Resolution
- Luminance
- Luminance uniformity
- Low-level luminance
- Contrast variation
- Display quality
- Display dynamics (e.g., jitter, flicker, update rate, and lag)
- Brightness controls

Installation criteria address visibility and access to EFVS controls and integration of EFVS in the cockpit.

The EFVS demonstration criteria address the flight and environmental conditions that need to be covered.

The FAA also intends to apply certification criteria relevant to high-intensity radiated fields (HIRF) and lightning protection.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 777F. Should the FedEx Express Corporation apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. T00001SE to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on Boeing 777F airplanes. It is not a rule of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type-certification basis for Boeing Model 777F airplanes modified by the FedEx Express Corporation.

1. Enhanced flight vision system (EFVS) imagery on the head-up display (HUD) must not degrade the safety of flight or interfere with the effective use of outside visual references for required pilot tasks during any phase of flight in which it is to be used.

2. To avoid unacceptable interference with the safe and effective use of the pilot compartment view, the EFVS device must meet the following requirements:

a. The EFVS design must minimize unacceptable display characteristics or artifacts (e.g., noise, ''burlap'' overlay, running water droplets) that obscure the desired image of the scene, impair the pilot's ability to detect and identify visual references, mask flight hazards, distract the pilot, or otherwise degrade task performance or safety.

b. Automatic control of EFVS display brightness must be sufficiently effective, in dynamically changing background (ambient) lighting conditions, to prevent full or partial blooming of the display that would distract the pilot, impair the pilot's ability to detect and identify visual references, mask flight hazards, or otherwise degrade task performance or safety. If automatic control for image brightness is not provided, it must be shown that a single manual setting is satisfactory for the range of lighting conditions encountered during a time-critical, high-workload phase of flight (e.g., low visibility instrument approach).

c. A readily accessible control must be provided that permits the pilot to immediately deactivate and reactivate display of the EFVS image on demand without removing the pilot's hands from the primary flight controls (yoke or equivalent) or thrust control.

d. The EFVS image on the HUD must not impair the pilot's use of guidance information, or degrade the presentation and pilot awareness of essential flight information displayed on the HUD, such as alerts, airspeed, attitude, altitude and direction, approach guidance, windshear guidance, traffic alert and collision avoidance system (TCAS) resolution advisories, or unusual attitude recovery cues.

e. The EFVS image and the HUD symbols, which are spatially referenced to the pitch scale, outside view, and image, must be scaled and aligned (i.e., conformal) to the external scene. In addition, the EFVS image and the HUD symbols, when considered singly or in combination, must not be misleading, cause pilot confusion or increase workload. Airplane attitudes or crosswind conditions may cause certain symbols (e.g., the zero-pitch line or flight path vector) to reach field-of-view limits such that they cannot be positioned conformally with the image and external scene. In such cases, these symbols may be displayed but with an altered appearance, which makes the pilot aware that they are no longer displayed conformally (for example, ''ghosting'').

f. A HUD system used to display EFVS images must, if previously certified, continue to meet all of the requirements of the original approval.

3. The safety and performance of the pilot tasks associated with the use of the pilot compartment view must not be degraded by the display of the EFVS image. Pilot tasks that must not be degraded by the EFVS image include:

a. Detection, accurate identification, and maneuvering, as necessary, to avoid traffic, terrain, obstacles, and other hazards of flight.

b. Accurate identification and utilization of visual references required for every task relevant to the phase of flight.

4. Use of EFVS for instrument approach operations must be in accordance with the provisions of § 91.175(l) and (m) and § 121.651 where applicable. Appropriate limitations must be stated in the operating limitations section of the airplane flight manual to prohibit the use of the EFVS for functions that have not been found to be acceptable.

Issued in Renton, Washington, on March 22, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–8739 Filed 4–11–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1013]

RIN 1625–AA09

Drawbridge Operation Regulation; Saginaw River, Bay City, MI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the drawbridge opening schedule for the Lake State Railway Bridge at mile 3.10, the Independence Bridge at mile 3.88, the Canadian National Railway Bridge at mile 4.94, the Liberty Street Bridge at mile 4.99, the Veterans Memorial Bridge at mile 5.60, and the Lafayette Street Bridge at mile 6.78, all over the Saginaw River at Bay City, MI. The previous regulation was confusing, outdated, and unnecessarily restrictive for both commercial and recreational vessels. The revised regulation will simplify the regulatory language, increase access through the drawbridges for all vessels, and provide for the reasonable needs of all traffic.

DATES: This rule is effective May 14, 2012.

ADDRESSES: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–1013 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1013 in the ''Keyword'' box, and then clicking ''Search''. This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Lee Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone (216) 902–6085, email *lee.d.soule@uscg.mil.* If you have questions on viewing material in the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 8, 2011, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulation; Saginaw River, Bay City, MI, in the **Federal Register** (76 FR 76637). We received one comment in response to the proposed rule supporting the NPRM as written. No public meeting was requested, and none was held.

Basis and Purpose

Lake Carriers Association (LCA), an organization representing U.S. shipping companies on the Great Lakes, requested that the existing drawbridge regulation for Saginaw River be reviewed and changed to make the regulation easier to understand and to remove restrictive drawbridge schedules for commercial vessels. The existing regulation was reviewed in its entirety for all drawbridges, vessel types, dates, and hours of operation.

Lake State Railway Bridge at mile 3.10 is a swing bridge that provides 7 feet vertical clearance in the closed position and unlimited clearance in the open position. The Independence Bridge at mile 3.88 is a bascule bridge that provides 22 feet vertical clearance in the closed position and unlimited clearance in the open position. The Canadian National Railway (CN RR) Bridge at mile 4.94 is a swing bridge that provides 8 feet of vertical clearance in the closed position and unlimited clearance in the open position. The Liberty Street Bridge at mile 4.99 is a bascule bridge that provides 25 feet of vertical clearance in the closed position and unlimited clearance in the open position. The Veterans Memorial Bridge at mile 5.60 is a bascule bridge that provides 15 feet of vertical clearance in the closed position and unlimited clearance in the open position. The Lafayette Street Bridge at mile 6.78 is a bascule bridge that provides 20 feet vertical clearance in the closed position and unlimited clearance in the open position. There is no alternate waterway for vessels entering or departing Saginaw River.

The draws of the Lake State Railway and Canadian Railway Bridges currently open on signal for all vessel traffic that requires a bridge opening, except that from December 16 through March 15 the bridges open on signal if at least 12 hours advance notice is provided.

The draws of the Independence Bridge, Liberty Street, Veterans Memorial, and Lafayette Street drawbridges open on signal from March 16 through December 15, except as follows: The draws need not open for the passage of vessels less than 50 gross tons from 6:30 a.m. to 8:30 a.m. and 3:30 p.m. to 5:30 p.m., except Saturdays, Sundays, and holidays observed in the locality. The draws need not open for the passage of downbound vessels over 50 gross tons from 7:30 a.m. to 8:30 a.m. and 4:30 p.m. to 5:30 p.m., except on Sundays, Federal holidays, and holidays observed in the locality. From 8 a.m. to 8 p.m. on Saturdays, Sundays, and Federal holidays, the Independence Bridge and Veterans Memorial bridges need not open for recreational vessels except from three minutes before to three minutes after the hour and half-hour, and the Liberty Street and Lafayette Street bridges need not open for recreational vessels except from three minutes before to three minutes after the quarter-hour and three-quarter hour. Currently, the draws of these bridges shall open on signal from December 16 through March 15 if at least 12 hours advance notice is provided.

The proposed drawbridge schedules and revised regulations were developed with all known stakeholders, including; Lake Carriers Association, Canadian Shipowners Association, local Coast Guard units, City of Bay City, MI, Michigan Department of Transportation (MDOT), Bay Harbor Marina, Pier 7 Marina, Liberty Harbor Marina, and Bay City Yacht Club.

Discussion of Comments and Changes

The Coast Guard received one comment supporting the NPRM as written. No changes to the proposed regulation have been made in this final rule. The revised regulation reflects current conditions and provides for the reasonable needs of all modes of transportation.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. This rule increases access through the drawbridges for all entities compared to the existing regulation and drawbridge schedule. All known marina owners and small entities were consulted during the development of this revised rule. Additionally, all vessels that do not require bridge openings may transit the drawbridges at any time.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under figure 2–1, paragraph (32)(e), of the instruction.

Under figure 2–1, paragraph (32)(e), of the instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard revises 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.647 to read as follow:

§ 117.647 Saginaw River.

(a) The draws of the Lake State Railway Bridge, mile 3.10, and the Canadian National Railway Bridge, mile 4.94, both in Bay City, shall open on signal; except that from January 1 through March 31, the draws shall open on signal if at least 12 hours advance notice is provided.

(b) The draws of the Independence Bridge, mile 3.88, Liberty Street Bridge, mile 4.99, Veterans Memorial Bridge, mile 5.60, and Lafayette Street Bridge, mile 6.78, all in Bay City, shall open on signal, except as follows:

(1) From April 15 through November 1, between the hours of 6:30 a.m. and 7 p.m., Monday through Friday, except federal holidays, the draws of the Independence and Veterans Memorial Bridges need open for the passage of recreational vessels only from three minutes before to three minutes after the hour and half-hour, and the Liberty Street and Lafayette Street bridges need open for the passage of recreational vessels only from three minutes before to three minutes after the quarter-hour and three-quarter hour.

(2) From January 1 through March 31, the draws of these bridges shall open on signal if at least 12 hours advance notice is provided.

Dated: March 12, 2012.

M. N. Parks,

Rear Admiral, U. S. Coast Guard Commander, Ninth Coast Guard District.

[FR Doc. 2012–8821 Filed 4–11–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0282]

RIN 1625–AA00

Safety Zone; Sunken Vessel, Puget Sound, Everett, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary Final rule.

SUMMARY: The Coast Guard is establishing a safety zone around the Vigor Marine Dry Dock, located in Everett, WA. This action is necessary to prevent maritime traffic from colliding with a sunken dry dock and associated debris, and to ensure the safety of the salvage crews on scene. It will do so by prohibiting vessels from entering or remaining in the safety zone unless authorized by the Captain of the Port or his Designated Representative.

DATES: This rule is effective in the CFR on April 12, 2012 through 11:59 p.m. on April 15, 2012. This rule is effective with actual notice for purposes of enforcement at 12 a.m. on April 2, 2012. This rule will remain in effect through 11:59 p.m. on April 15, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2012–0282 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0282 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email ENS Nathaniel P. Clinger, Waterways Management Division, Coast Guard Sector Puget Sound; Coast Guard; telephone 206–217–6045; email *SectorPugetSoundWWM@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing a NPRM would be contrary to public interest since immediate action is necessary to protect vessels, persons, and salvage crews in Everett, WA, from hazards created by a sunken dry dock requiring emergency salvage operations. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Normal notice and comment procedures cannot be followed due to the immediate threat of collision and/or exposure to hazardous pollutants posed by the sunken vessel and associated pollution response and salvage operations.

Background and Purpose

On March 18, 2012 at approximately 12:46 p.m. the floating dry dock in which the 136 foot TUG INVADER was laying on blocks was found to have capsized and partially sank. As a result the Coast Guard established a 100 yard safety zone around the Vigor Marine Dry Dock in Everett, WA. On March 22, 2012 it was determined that a hard containment boom must be tied to the existing long log boom in place, which is outside of the original established safety zone. Due to these operational requirements this rule establishes a 200 yard safety zone surrounding the dry dock. As salvage operations continue to recover the floating dry dock, salvage equipment, which may include cranes and vessels utilizing dive teams that will require this zone to ensure safety. Enforcement of this zone will commence at 12 a.m. on April 2, 2012. The safety zone created by this rule is necessary to help ensure the safety of maritime public and the personnel involved in salvage operations. It prevents navigation in areas that may contain sunken obstructions, and debris.

Discussion of Rule

The Coast Guard is establishing a safety zone encompassing all waters within 200 yards of Vigor Marine Dry Dock in Everett, WA. Vessels wishing to enter the zone must request permission for entry by contacting the Joint Harbor Operation Center at (206) 217–6001 or Vessel Traffic Service Puget Sound on VHF–FM CH 14. Once permission for entry is granted vessels must proceed at a minimum speed for safe navigation.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

Executive Orders 13563, Improving Regulation and Regulatory Review, and 12866, Regulatory Planning and Review, direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this regulation under Executive Order 12866. This rule is not a significant regulatory action due to being limited in size and duration.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit the affected waterway during the period mentioned. This safety zone will not have a significant economic impact on a substantial number of small entities for the following reason. The zone established in this rule is limited in size and short in duration.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. An environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

■ 2. Add a temporary § 165.T13–213 to read as follows:

§ 165.T13–213 Safety Zone; Sunken Vessel, Puget Sound, Everett, WA.

(a) *Location:* The following area is designated as a safety zone: All waters within 200 yards of the Vigor Marine Dry Dock in Everett, WA.

(b) *Regulations:* In accordance with the general regulations in 33 CFR 165, Subpart C, vessels wishing to enter the zone must request permission for entry by contacting the Joint Harbor Operation Center at (206) 217–6001 or Vessel Traffic Service Puget Sound on VHF–FM CH 14. Once permission for entry is granted vessels must proceed at a minimum speed for safe navigation.

(c) *Effective Dates and Enforcement Periods:* This rule will be effective and enforced from 12 a.m. on April 2, 2012 through 11:59 p.m. on April 15, 2012, unless cancelled sooner by the Captain of the Port.

Dated: March 30, 2012.

S. J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. 2012–8757 Filed 4–11–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–1005]

RIN 1625–AA00

Safety Zone; Marina Salvage, Bellingham Bay, Bellingham, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in and around the Squalicum Harbor Marina, located in Bellingham, WA. This action is necessary to ensure the safety of the maritime public and the on-scene law enforcement, and salvage vessels by preventing contact with associated debris, and sunken vessels, and will do so by prohibiting vessels from entering or remaining in the safety zone unless authorized by the Captain of the Port or his Designated Representative.

DATES: This rule is effective April 12, 2012 through 11:59 p.m. April 13, 2012. The safety zone has been enforced with actual notice since 12 a.m. on April 5, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–1005 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1005 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Ensign Nathaniel P. Clinger, Waterways Management Division, Coast Guard Sector Puget Sound; Coast Guard; telephone 206–217–6323, email *SectorPugetSoundWWM@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing a NPRM would be contrary to public interest since immediate action is necessary to protect vessels, persons and law enforcement vessels in

Bellingham, WA, from hazards created by a marina fire, which produced sunken vessels, and requires emergency salvage operations. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Normal notice and comment procedures cannot be followed due to the immediate threat of collision and/or exposure to hazardous debris associated with the marina salvage operations.

Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 46 U.S.C. chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

On March 30 at approximately 5:32 a.m. the Coast Guard received a report that a house boat exploded, in the Squalicum Marina in the Bellingham Harbor, which ignited a boat house and sunk multiple vessels. On April 4, 2012 the Coast Guard was notified that the salvage operations to recover approximately 10 sunken vessels will require a safety zone that exceeds the timeline of the initial zone. Due to ongoing salvage operations, which may include cranes and vessels utilizing dive teams, the Coast Guard will establish a safety zone of all waters of the Squalicum Harbor Marina and all waters within 200 yards of the entrance to the marina, located in Bellingham, WA. Enforcement of this zone will commence at 12 a.m. on April 5, 2012. The safety zone created by this rule is necessary to help ensure the safety of the maritime public and the personnel involved in the salvage operations. It prevents navigation in areas that may contain debris and hazardous materials produced from the boat house and damaged vessels.

Discussion of Rule

The Coast Guard is establishing a safety zone which encompasses all waters of the Squalicum Harbor Marina and all waters within 200 yards of the entrance, in Bellingham, WA. Vessels wishing to enter the zone must request permission for entry by contacting the on-scene patrol craft on VHF CH 13 or Joint Harbor Operation Center at (206) 217–6001. Once permission for entry is granted vessels must proceed at a minimum speed necessary for safe navigation.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. This rule is not a significant regulatory action due to being limited in size and duration.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators vessels intending to transit the affected waterway during the period mentioned. This safety zone will not have a significant economic impact on a substantial number of small entities because the zone established in this rule is limited in size and short in duration.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. An environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under ADDRESSES.

List of Subjects 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

■ 2. Add a temporary § 165.T13–215 to read as follows:

§ 165.T13–215 Safety Zone; Marina Salvage, Bellingham Bay, Bellingham, WA.

(a) *Location.* The following area is designated as a safety zone: All waters of the Squalicum Harbor Marina and all waters within 200 yards of the entrance to the marina, located in Bellingham, WA.

(b) *Regulations.* In accordance with the general regulations in 33 CFR 165, Subpart C, vessels wishing to enter the zone must request permission for entry by contacting the Joint Harbor Operation Center at (206) 217–6001 or the on-scene patrol craft on VHF CH 13. Once permission for entry is granted vessels must proceed at a minimum speed necessary for safe navigation.

(c) *Enforcement period.* This rule will be effective from 12 a.m. on April 5, 2012, through 11:59 p.m. on April 13, 2012, unless cancelled sooner by the Captain of the Port.

Dated: April 4, 2012.

S. J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. 2012–8876 Filed 4–10–12; 11:15 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–9657–7]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the A & F Material Reclaiming, Inc. Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Deletion of the A & F Material Reclaiming, Inc. Superfund Site (Site), located in Greenup, Illinois from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Illinois, through the Illinois Environmental Protection Agency (IEPA), because EPA has determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final deletion is effective June 11, 2012 unless EPA receives adverse comments by May 14, 2012. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1983–0002, by one of the following methods:

- *http://www.regulations.gov:* Follow online instructions for submitting comments.
- *Email:* Gladys Beard, NPL Deletion Process Manager, at *beard.gladys@epa.gov* or Janet Pope, Community Involvement Coordinator, at *pope.janet@epa.gov.*
- *Fax:* Gladys Beard, NPL Deletion Process Manager, at (312) 697–2077.
- *Mail:* Gladys Beard, NPL Deletion Process Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–7253; or Janet Pope, Community Involvement Coordinator,

U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 353–0628 or (800) 621–8431.

• *Hand delivery:* Janet Pope, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–1983–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at:

• U.S. Environmental Protection Agency—Region 5, 77 West Jackson Boulevard, Chicago, IL 60604. Phone: (312) 353–1063. Hours: Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

• Greenup City Clerk's Office, Greenup Municipal Building, 115 Cumberland Avenue, Greenup, IL 62428. Phone: (217) 923–3401. Hours: Monday through Friday, 7:30 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Gladys Beard, NPL Deletion Process Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 353–2315, or *beard.gladys@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 5 is publishing this direct final Notice of Deletion of the A & F Material Reclaiming, Inc. Superfund Site from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

Because EPA considers this action to be noncontroversial and routine, this action will be effective June 11, 2012 unless EPA receives adverse comments by May 14, 2012. Along with this direct final Notice of Deletion, EPA is co-publishing a Notice of Intent to Delete in the ''Proposed Rules'' section of the **Federal Register**. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion, and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the A & F Material Reclaiming, Inc. Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

1. Responsible parties or other persons have implemented all appropriate response actions required;
2. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or
3. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

1. EPA consulted with the State of Illinois prior to developing this direct final Notice of Deletion and the Notice of Intent to Delete co-published today in the ''Proposed Rules'' section of the **Federal Register**.
2. EPA has provided the State with 30 working days for review of this notice and the parallel Notice of Intent to Delete prior to their publication today, and the State, through IEPA, has concurred on the deletion of the Site from the NPL.
3. Concurrently with the publication of this direct final Notice of Deletion, a notice of the availability of the parallel Notice of Intent to Delete is being published in a major local newspaper, the Times Courier News, located in Charleston, Illinois. The newspaper notice announces the 30-day public comment period concerning the Notice

of Intent to Delete the Site from the NPL.

4. EPA placed copies of documents supporting the proposed deletion in the deletion docket and made these items available for public inspection and copying at the Site information repositories identified above.

5. If adverse comments are received within the 30-day public comment period on this deletion action, EPA will publish a timely notice of withdrawal of this direct final Notice of Deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the Notice of Intent to Delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site Background and History

The A & F Material Reclaiming, Inc. Superfund Site (CERCLIS ID# ILD980397079) is located on approximately four acres of land on the western border of the Village of Greenup, in east-central Illinois. The Site, which lies on the west side of the village, is bounded by open farmland and woodland, the local wastewater treatment plant, and private residences; fairgrounds lie to the southwest. The Site has a slope toward the Embarras River, which lies about 600 feet to the north. Drainage from the Site reaches the river by way of a ditch along a former railroad right-of-way west of the Site and east of the municipal wastewater treatment plant. The local wastewater treatment plant has several lagoons and the plant discharges the treated water into the ditch along the railroad right-of-way.

Three distinct aquifers exit at the Site: Alluvium till, present at or near ground surface; sand and gravel, present at shallow depths below ground surface, and bedrock. The shallow aquifer is a poor water producer and is not used as a source of water supply. However, it does furnish recharge to the underlying sand and gravel. The alluvium forms an essentially level surface and contains groundwater at shallow depths in the range of 8 to 12 feet below grade. According to the measured water levels, groundwater flow is directed downslope to the west and north of the Site. No private wells have been found north or west of the Site. The sand and gravel outwash aquifer is a regionally significant unit which is present beneath the entire Site and receives recharge from the overlying alluvium. In the outwash sand and gravel aquifer, groundwater flow is generally downslope from the highlands east of the Site, and flow in the level section of the study area is directed northward toward the Embarras River. Discharge is also directed toward the Embarras River. The bedrock aquifer is not significant in the area of the Site. Water contained in the fractured section of the Pennsylvanian bedrock is present under strong artesian conditions. Recharge of the bedrock aquifer probably occurs from overlying units located elsewhere where water levels are higher than those observed in the study area. Based upon water level data from the remedial investigation, neither of the unconsolidated aquifers encountered on-site discharges to the drainage ditch. The lagoons constructed on site during operation of the facility were excavated into the unsaturated portion of the alluvial aquifer.

The historic use of the Site has been for industrial purposes. However, there have not been any industrial activities at the Site since the facility closed in 1980. The A & F Material Reclaiming facility began operations in March 1977 as a recycling plant. The facility processed waste materials such as oil, sludge, caustics, and sulfuric acid into fuel oil and fire retardant chemicals. There were numerous violations of the operating permits issued by IEPA. Within a year of operating, four storage lagoons overflowed, contaminating the surrounding soil and water drainage pathway to the Embarras River. In addition, some of the steel storage tanks failed on several occasions, releasing their contents on the Site. These tanks held mixtures of waste oils, sludges, spent caustics, spent acids, contaminated water, and other waster products. Present land use for the surrounding area is residential, commercial, and recreational (fairgrounds are located southwest of the Site). Currently no groundwater underlying the Site is used as a drinking water source.

From December 1980 through December 1982 there were several removal actions at the Site in which contaminated soils, sediments, tank, and buildings were removed and disposed off site. These actions included lowering the level of waste in the lagoons, diking, trenching, and removing drums and wastes off site. In addition, a temporary cap was placed over a portion of the consolidated sludge on site.

In December 1982 the Site was included on the Proposed NPL (47 FR 58476). The Site was finalized on the NPL on September 8, 1983 (48 FR 40674). In November 1983 an Initial Remedial Measure was implemented to address remaining site contaminants in tanks and drums. The remaining on-site waste included approximately 153,000 gallons of contaminated liquids in tanks, 16,000 gallons of contaminated oil in tanks, and 20 drums with unknown contents. All tank liquids, oils, and drums were disposed off site at an approved facility through the Initial Remedial Measure.

On September 12, 1984, a Partial Consent Decree was entered into by four of the potentially responsible parties, which outlined a remedial action plan that included a phased approach for cleaning up the Site. The first phase included the remedial investigation and the feasibility study; the second phase was an immediate removal action to address the threatened release of contaminates from the two lagoons; the third phase involved removal and disposal of contaminated soils and sediments, removal and disposal of the building and equipment, final site grading, air monitoring, and site security; and the final phase of the remedial action plan involved closure and groundwater monitoring requirements.

Remedial Investigation and Feasibility Study

The remedial investigation report did not include a formal baseline risk assessment. Since the lagoon sludge, wastewater, oil, and tank waste were removed under the Interim Remedial Measure, they posed no environmental impacts or adverse health effects to the neighboring community. The primary concerns associated with the Site were from ingestion or direct contact exposures to the soil, sediment, groundwater, and surface water. Soils in the area of the tank farm were contaminated and posed an environmental threat. Several sediment samples taken from the drainage ditch showed low levels of polynuclear aromatic hydrocarbons, but sediments from the river did not have any substantial contamination. Neither the drainage ditch nor the river showed any contamination above background levels.

Data from groundwater monitoring wells showed elevated levels of sulfate, total dissolved solids (TDS), and oil and grease. Additionally, several metals were detected at levels higher than background and in some cases higher than the IEPA standard for groundwater. Because of the dilution effect between the groundwater and surface water, it was expected that the contaminated groundwater would not cause contamination in the river. Also, the planned removal of contaminated materials from the Site would remove the primary source of contamination to the groundwater. The remedial investigation concluded there was a high flow rate through the sand and gravel aquifer, which would allow for rapid flushing of any residual contaminants.

Selected Remedy

1985 and 1986 Enforcement Decision Document (EDD) Findings:

EPA issued an EDD for Operable Unit 1 (OU1) on June 14, 1985 that addressed the soil, sediments, building, and equipment. The goal of this remedy was to remove soils found with contamination above action levels for site contaminants of concern (COCs) and to remove on-site buildings in order to protect public health, welfare, and the environment. The remedy for OU1 included:

- All soils, surface and subsurface, contaminated above the recommended action levels were to be removed and disposed at an off-site facility;
- Facility equipment and building structures were to be cleaned, dismantled, removed, and disposed at an off-site facility;
- Site grading to eliminate ponding;
- Maintenance of a vegetative cover to prevent erosion; and
- Groundwater monitoring to confirm that no further soil removal was required.

On August 14, 1986 EPA issued an EDD for Operable Unit 2 (OU2) that addressed groundwater. The goal of this remedy was to restore groundwater to below Maximum Concentration Levels (MCLs) in order to protect public health, welfare, and the environment. The remedy for OU2 included:

- Establishing a groundwater monitoring program to test whether all residual groundwater contamination remaining after the cleanup would steadily decrease to safe levels by natural dilution and purging to the Embarras River without causing violation of the water quality standards of the river;
- Establishing adequate institutional controls so that drinking water wells are not placed in the contaminated groundwater areas during the period of natural dilution and purging; and
- Establishing procedures for regular review of monitoring data until safe levels are reached or data contradicting the feasibility study conclusions demonstrates the need to reevaluate the remedy.

2010 ESD Findings:

On May 24, 2010 an Explanation of Significant Differences (ESD) was signed by EPA. The purpose of the ESD was to eliminate iron, manganese, sulfate, and TDS as site contaminants of concern from the groundwater cleanup remedy selected in the 1986 EDD for OU2. These contaminants were removed because the action levels for these four parameters are secondary MCLs, which are non-enforceable guidelines regulating contaminants that may cause cosmetic or aesthetic effects in drinking water. Furthermore, review of groundwater data by EPA concluded that these constituents are naturally occurring, do not pose a risk to human health and the environment, and are stable or decreasing in concentration.

Response Actions

With the implementation of the OU1 remedy, an additional 1,600 tons of soil and sludge, 1,300 cubic yards of polychlorinated biphenyl (PCB)-contaminated soil, and a process building with contaminated equipment were removed from the Site. The soils remaining on site were sampled and analyzed prior to placing clean fill over the area. All compounds analyzed for, including PCBs, were at non-detectable limits. Only phenols and benzoic acid were detected in two pocket areas, but the detected levels were below action levels. Soil and sediment action levels in the 1985 EDD for OU1 remain protective. Any remaining residual soil or sediment contamination are at levels comparable to concentrations found naturally in the environment and do not present any environmental or public health risks. The entire area was then filled with clean soil, graded, and vegetated.

The groundwater monitoring program was agreed to by the Consenting Defendants in 1988 and documented in the August 1988 Remedial Action Plan as required by the August 14, 1986 EDD for OU2. EPA approved the design, including plans and specifications for well placement, project health and safety plan, and quality assurance project plan in May 1990. Well construction was completed, and a final inspection was conducted on July 9, 1990.

EPA signed the Preliminary Close-Out Report, documenting that all construction activities for the final operable unit at the Site had been completed on September 24, 1992. In 2000, as part of the institutional controls requirements for the Site, Cumberland County and the Village of Greenup adopted ordinances restricting groundwater use on approximately 68 acres that include the A & F Material Reclaiming Site and some surrounding areas. The ordinances were intended to prevent contact and use of the contaminated groundwater at and near the Site until groundwater quality reaches safe levels, in accordance with the 1986 EDD for OU2.

With the signing of the May 24, 2010 ESD, all groundwater cleanup levels have been attained and groundwater monitoring is no longer required. The 1986 EDD for OU2 specified that "institutional controls will be required until groundwater quality returns to background levels or below the State and Federal criteria shown in Table 2" (Table 1). Because groundwater cleanup levels have been attained, EPA no longer requires that institutional controls be maintained at the Site.

Cleanup Goals

Under the August 1988 Remedial Action Plan required by the August 14, 1986 EDD for OU2, several additional monitoring wells were installed and a few existing wells were abandoned. Twenty parameters listed in the 1986 EDD for OU2 (Table 1) were to be periodically monitored until their concentrations dropped below the action levels specified in the EDD. The action levels were based upon MCLs and secondary MCLs of the Safe Drinking Water Act. Elimination of a parameter in a given well could occur when that parameter had not been detected above the action limits per the procedures in the August 1988 Remedial Action Plan.

TABLE 1—CONTAMINANTS OF CONCERN

[From the 1986 Record of Decision for the A & F Material Reclaiming Superfund Site]

Contaminant of concern	Action level (mg/l)
Trichloroethylene	0.005
Benzene	0.005
Phenolics	0.001
Sulfates	250
Nitrates	10
Total Dissolved Solids	500
Oil and Grease	0.1

TABLE 1—CONTAMINANTS OF CONCERN—Continued

[From the 1986 Record of Decision for the A & F Material Reclaiming Superfund Site]

Contaminant of concern	Action level (mg/l)
Chloride	250
Arsenic	0.05
Barium	1
Cadmium	1.01
Chromium	0.05
Copper	1.02
Iron	0.3
Lead	1.05
Manganese	0.05
Nickel	13.4
Silver	0.005
Thallium	0.013
Zinc	1

Note: Toxicity, Conductivity, and Aluminum were listed but were not given an action level and were not included in the long-term monitoring plan.

Between 1990 and 1999 sixteen of the twenty monitoring parameters were eliminated as their concentrations had dropped below their respective action levels. Following the March 1999 sampling event, only four of the original twenty parameters were monitored: Iron, manganese, sulfate, and TDS. These parameters were eliminated as site contaminants of concern in the 2010 ESD. With the elimination of the four remaining site contaminants of concern, the action levels identified in the 1986 EDD for OU2 for these contaminants are no longer applicable or relevant and appropriate. Therefore, all groundwater cleanup levels have been attained and groundwater monitoring will no longer be required. Cumberland County and the Village of Greenup were notified by EPA in May 2010 that no further groundwater monitoring will be required. As noted previously, confirmatory soil sampling has indicated that all compounds sampled and analyzed for yielded either non-detectable levels or levels that are still below action levels for soil. All monitoring conducted for surface water and sediments in the Embarras River were below sediment action levels and surface water quality criteria for all groundwater parameters listed in the EDD, as modified by the ESD. The COCs that were listed in the 1985 EDD included the following: Trichloroethylene, benzene, sulfates, TDS, oil and grease, copper, silver, zinc, lead, chromium (+6), barium, thallium, phenolics, total organic halogens, nitrates, chloride, conductivity, nickel, aluminum, iron, manganese, cadmium, and arsenic.

Operation and Maintenance

Operation and maintenance activities are no longer required at this Site.

Five-Year Reviews

Policy five-year reviews were completed for the A & F Material Reclaiming Site on September 27, 2000; September 29, 2005; and June 30, 2010. The June 30, 2010 five-year review concluded that the site remedy was protective of human health and the environment. No issues or recommendations were identified as part of this review. This five-year review also concluded that the cleanup goals for soil and groundwater have been achieved and that hazardous wastes no longer remain on site that would prohibit unlimited use or unrestricted exposure. Therefore, five-year reviews are no longer required at the A & F Material Reclaiming Superfund Site.

Community Involvement

Public participation activities have been satisfied as required in CERCLA Section 113(k), 42 U.S.C. 9613(k), and CERCLA Section 117, 42 U.S.C. 9617. Documents in the deletion docket, which EPA relied on for recommendation of the deletion of this Site from the NPL, are available to the public in the information repositories and at *www.regulations.gov.*

Determination That the Site Meets the Criteria for Deletion in the NCP

The NCP (40 CFR 300.425(e)) states that a site may be deleted from the NPL when no further response action is appropriate. EPA, in consultation with the State of Illinois, has determined that the responsible parties have implemented all response actions required, and no further response action by responsible parties is appropriate.

V. Deletion Action

EPA, with concurrence from the State of Illinois through IEPA, has determined that all appropriate response actions under CERCLA have been completed. EPA received concurrence from the State of Illinois on January 10, 2012. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective June 11, 2012 unless EPA receives adverse comments by May 14, 2012. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final Notice of Deletion before the effective date of the deletion, and it will not take effect. EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, and Water supply.

Dated: March 19, 2012.

Susan Hedman,

Regional Administrator Region 5.

For the reasons set out in this document, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

■ 2. Table 1 of Appendix B to part 300 is amended by removing ‘‘A & F Material Reclaiming, Inc.’’, ‘‘Greenup’’, ‘‘IL’’.

[FR Doc. 2012–8855 Filed 4–11–12; 8:45 am]

BILLING CODE 6560–50–P

Federal Register

Vol. 77, No. 71

Thursday, April 12, 2012

Proposed Rules

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2012–0015]

RIN 3170–AA21

Truth in Lending (Regulation Z)

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Proposed rule; request for public comment.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is proposing to amend Regulation Z, which implements the Truth In Lending Act, and the official interpretation to the regulation, which interprets the requirements of Regulation Z. Regulation Z generally limits the total amount of fees that a credit card issuer may require a consumer to pay with respect to an account, limiting fees to 25 percent of the credit limit in effect when the account is opened. Regulation Z currently states that this limitation applies prior to account opening and during the first year after account opening. The proposal requests comment on whether to amend Regulation Z to apply the limitation only during the first year after account opening.

DATES: Comments must be received on or before June 11, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2012–0015 or Regulatory Identification Number (RIN) 3170–AA21, by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Monica Jackson, Office of the Executive Secretary, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier in Lieu of Mail:* Monica Jackson, Office of the Executive Secretary, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20552.

All submissions must include the agency name and docket number or RIN for this rulemaking. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect the documents by calling (202) 435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or social security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Gregory Evans, Counsel, or Benjamin K. Olson, Managing Counsel, Division of Research, Markets, and Regulations, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20552, at (202) 435–7000.

SUPPLEMENTARY INFORMATION:

I. Background

The Credit Card Accountability Responsibility and Disclosure Act of 2009 (Credit Card Act) was signed into law on May 22, 2009.[1] The Credit Card Act primarily amended the Truth in Lending Act (TILA) and instituted new substantive and disclosure requirements to establish fair and transparent practices for open-end consumer credit plans.

The Credit Card Act added TILA Section 127(n)(1), which states that ''[i]f the terms of a credit card account under an open end consumer credit plan require the payment of any fees (other than any late fee, over-the-limit fee, or fee for a payment returned for insufficient funds) by the consumer in the first year during which the account is opened in an aggregate amount in excess of 25 percent of the total amount of credit authorized under the account when the account is opened,'' then ''no payment of any fees (other than any late fee, over-the-limit fee, or fee for a payment returned for insufficient funds) may be made from the credit made available under the terms of the account.''[2]

On January 12, 2010, the Federal Reserve Board of Governors (Board) issued a final rule implementing new TILA Section 127(n) in 12 CFR 226.52(a).[3] Section 226.52(a) limits the total amount of fees that a credit card issuer may require a consumer to pay with respect to an account to 25 percent of the credit limit in effect when the account is opened. Under the January 2010 final rule, this limitation applied only during the first year after account opening.[4] This rule became effective on February 22, 2010.

On April 8, 2011, the Board issued a final rule expanding § 226.52(a) to apply to fees the consumer is required to pay with respect to an account prior to account opening.[5] The change was based on the Board's understanding that certain credit card issuers were ''requiring consumers to pay application or processing fees prior to account opening that, when combined with other fees charged to the account after account opening, exceed 25 percent of the account's initial credit limit.''[6] The Board viewed this practice as ''inconsistent with the intent of [TILA] Section 127(n)(1) insofar as it alters the statutory relationship between the costs and benefits of opening a credit card account.''[7] The Board's change to § 226.52(a) was scheduled to become effective on October 1, 2011.[8]

On July 20, 2011, a credit card issuer filed a lawsuit in the United States District Court for the District of South Dakota, alleging that the Board exceeded its authority by expanding § 226.52(a) to apply to fees the consumer is required to pay prior to account opening.[9] On July 21, 2011, the Board's rulemaking authority to implement the provisions of TILA transferred to the Bureau pursuant to Sections 1061 and 1100A of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank

[1] Public Law 111–24, 123 Stat. 1734 (2009).

[2] 15 U.S.C. 1637(n)(1).

[3] *See* 75 FR 7658, 7819 (Feb. 22, 2010).

[4] *Id.*

[5] 76 FR 22948, 23002 (Apr. 25, 2011). The Board proposed this provision for comment in November 2010. 75 FR 67458, 67475 (Nov. 2, 2010).

[6] 76 FR at 22977.

[7] *Id.*

[8] *Id.* at 22948.

[9] *See First Premier Bank, et al.* v. *United States Consumer Fin. Prot. Bureau, et al.*, — F. Supp. 2d. —, 2011 WL 4458785 (D.S.D. Sept. 23, 2011).

Act).[10] On August 5, 2011, the card issuer filed a motion for a preliminary injunction, asking the court to postpone the October 1, 2011 effective date with respect to the application of § 226.52 to fees paid prior to account opening. The district court granted the motion for a preliminary injunction on September 23, 2011. As a result of the court's order, the portion of the Board's 2011 final rule applying § 226.52(a) to pre-account opening fees has not become effective.

On December 22, 2011, the Bureau issued an interim final rule to reflect its assumption of rulemaking authority over Regulation Z.[11] The interim final rule made only technical changes to Regulation Z, such as noting the Bureau's authority and renumbering Regulation Z as 12 CFR part 1026. Accordingly, the provision addressed in this proposal and in the litigation discussed above is properly cited as 12 CFR 1026.52(a).

II. Legal Authority

The Bureau is issuing this proposal pursuant to its authority under TILA and the Dodd-Frank Act. Effective July 21, 2011, Section 1061 of the Dodd-Frank Act transferred to the Bureau the ''consumer financial protection functions'' previously vested in certain other Federal agencies. The term ''consumer financial protection functions'' is defined to include ''all authority to prescribe rules or issue orders or guidelines pursuant to any Federal consumer financial law, including performing appropriate functions to promulgate and review such rules, orders, and guidelines.'' [12] TILA is a Federal consumer financial law.[13] Accordingly, effective July 21, 2011, except with respect to persons excluded from the Bureau's rulemaking authority by Section 1029 of the Dodd Frank Act, the authority of the Board to issue regulations pursuant to TILA transferred to the Bureau.

TILA, as amended by the Dodd-Frank Act, authorizes the Bureau to ''prescribe regulations to carry out the purposes of [TILA].'' [14] These regulations may contain such classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for any class of transactions, that in the Bureau's judgment are necessary or proper to effectuate the purpose of TILA, facilitate compliance with TILA, or prevent circumvention or evasion of TILA.[15]

III. Summary of the Proposed Rule

The Bureau is proposing to amend 12 CFR 1026.52(a) to resolve the uncertainty caused by the litigation discussed above. Specifically, the Bureau is proposing to amend § 1026.52(a) to provide that the limitation on credit card fees applies only during the first year after account opening. The Bureau is also proposing to make corresponding amendments to the Official Interpretations of § 1026.52(a).

IV. Section 1022(b)(2) of the Dodd-Frank Act

In developing the proposed rule, the Bureau has conducted an analysis of potential benefits, costs, and impacts,[16] and has consulted or offered to consult with the prudential regulators and the Federal Trade Commission, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies.

The proposal provides that the limitation on credit card account fees in § 1026.52(a) applies only during the first year after account opening. If the proposal is adopted, fees that a consumer is required to pay prior to account opening will not be subject to the limitation in § 1026.52(a).

The Bureau believes that the proposal, if adopted, may impose potential costs on consumers by permitting covered persons to collect fees that would be disallowed absent the proposal. Covered persons should benefit from clarification of the scope of § 1026.52(a) to resolve any uncertainty created by the litigation discussed above. The proposed rule would also permit covered persons to collect fees that would be prohibited absent the proposed rule. The Bureau does not expect the proposal to impose costs on covered persons. All methods of compliance under current law will remain available to covered persons if the proposal is adopted. Thus, a covered person who is in compliance with current law need not take any additional action if the proposal is adopted.

Finally, the proposed rule would have no unique impact on insured depository institutions or insured credit unions with $10 billion or less in assets as described in section 1026 of the Dodd-Frank Act, nor would the proposed rule have a unique impact on rural consumers.

The Bureau requests comments on the potential benefits, costs, and impacts of the proposal.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations.[17] The RFA defines a ''small business'' as a business that meets the size standard developed by the Small Business Administration pursuant to the Small Business Act.[18]

The RFA generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives prior to proposing a rule for which an IRFA is required.[19]

An IRFA is not required for the proposal because the proposal, if adopted, would not have a significant economic impact on any small entities. The Bureau does not expect the proposal to impose costs on covered persons. All methods of compliance under current law will remain available to small entities if the proposal is adopted. Thus, a small entity that is in compliance with current law need not take any additional action if the proposal is adopted. Instead, the overall

[10] Public Law 111–203 (2010). *See* 12 U.S.C. 5581; 15 U.S.C. 1604(a); Designated Transfer Date, 75 FR 57252 (Sept. 20, 2010).

[11] 76 FR 79768 (Dec. 22, 2011).

[12] Public Law 111–203, Section 1061(a)(1). Effective on the designated transfer date, the Bureau was also granted ''all powers and duties'' vested in each of the Federal agencies, relating to the consumer financial protection functions, on the day before the designated transfer date.

[13] Public Law 111–203, Section 1002(14) (defining ''Federal consumer financial law'' to include the ''enumerated consumer laws''); *id.* Section 1002(12) (defining ''enumerated consumer laws'' to include TILA).

[14] Public Law 111–203, Section 1100A(2); 15 U.S.C. 1604(a).

[15] *Id.*

[16] Specifically, Section 1022(b)(2)(A) calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Act; and the impact on consumers in rural areas. This discussion considers the impacts of the proposed rule relative to existing law.

[17] 5 U.S.C. 601 *et seq.* The Bureau is not aware of any governmental units or not-for-profit organizations to which the proposal would apply.

[18] 5 U.S.C. 601(3). The Bureau may establish an alternative definition after consultation with the Small Business Administration and an opportunity for public comment.

[19] 5 U.S.C. 609.

effect of the proposal would be to narrow the compliance obligations under § 1026.52(a) for covered persons and to give covered persons additional certainty about how to comply with § 1026.52(a).

Accordingly, the undersigned certifies that this proposal, if adopted, would not have a significant economic impact on a substantial number of small entities.

VI. Paperwork Reduction Act

The collection of information related to this notice of proposed rulemaking has been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) and assigned OMB Control Number 3170–0015. Under the Paperwork Reduction Act, the Bureau may not conduct or sponsor, and a person is not required to respond to, an information collection unless the information collection displays a currently valid control number assigned by OMB. As discussed below, the Bureau does not believe that this proposed rule imposes any new collection of information or any increase to the previously approved estimated burden associated with the information collection in Regulation Z.

The collection of information, if any, in Regulation Z, 12 CFR part 1026. The information collection in Regulation Z is required to provide benefits for consumers and is mandatory.[20] The respondents and/or recordkeepers are creditors and other entities subject to Regulation Z, including for-profit financial institutions, small businesses, and institutions of higher education. Under § 1026.25, creditors are required to retain evidence of compliance for twenty-four months, but Regulation Z does not specify the types of records that must be maintained.

If this proposal to Regulation Z is adopted, card issuers will not be required to comply with § 1026.52(a) with respect to fees the consumer is required to pay prior to account opening. The Bureau believes that any burden associated with updating compliance under the proposed provisions is already accounted for in the previously approved burden estimates associated with the collection in Regulation Z under the Board's January 2010 Final Rule estimates. That rule imposed a similar limitation on fees.[21] Accordingly, for the reasons stated above, the Bureau estimates that there would not be an increase in the one-time or ongoing burden to comply with the requirements under proposed § 1026.52(a).

Although the Bureau does not believe that the proposed rule imposes any new collection of information or any increase to the previously approved estimated burden associated with the collection in Regulation Z, the Bureau solicits comment on the proposed modification to § 1026.52(a) or any other aspect of the proposal for purposes of the PRA. Comments on the collection of information requirements should be sent to the Office of Management and Budget, Attention: Desk Officer for the Consumer Financial Protection Bureau, Office of Information and Regulatory Affairs, Washington, DC 20503, or by the Internet to *http://oira_submission@omb.eop.gov,* with copies to the Bureau at the address previously specified.

Text of Proposed Revisions

Certain conventions have been used to highlight the proposed changes to the text of the regulation and official interpretation. New language is shown inside ►bold-faced arrows◄, while language that would be deleted is set off with **[**bold-faced brackets**]**.

List of Subjects in 12 CFR Part 1026

Advertising, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

Authority and Issuance

For the reasons set forth above, the Bureau proposes to amend Part 1026 of Chapter X in Title 12 of the Code of Federal Regulations as follows:

PART 1026—TRUTH IN LENDING (REGULATION Z)

1. The authority citation for Part 1026 continues to read as follows:

Authority: 12 U.S.C. 5512, 5581; 15 U.S.C. 1601 et seq.

Subpart G—Special Rules Applicable to Credit Card Accounts and Open-End Credit Offered to College Students

2. In § 1026.52, revise paragraph (a) to read as follows:

§ 1026.52 Limitations on fees.

(a) *Limitations* **[***prior to account opening and***]** *during first year after account opening.* (1) *General rule.* Except as provided in paragraph (a)(2) of this section, the total amount of fees a consumer is required to pay with respect to a credit card account under an open-end (not home-secured) consumer credit plan **[**prior to account opening and**]** during the first year after account opening must not exceed 25 percent of the credit limit in effect when the account is opened. For purposes of this paragraph, an account is considered open no earlier than the date on which the account may first be used by the consumer to engage in transactions.

* * * * *

Supplement I to Part 1026—Official Interpretations

3. In Paragraph 52(a), revise to read as follows:

Section 1026.52—Limitations on Fees

52(a) Limitations **[***prior to account opening and***]** *during first year after account opening.*

52(a)(1) General rule.

1. *Application.* The 25 percent limit in § 1026.52(a)(1) applies to fees that the card issuer charges to the account as well as to fees that the card issuer requires the consumer to pay with respect to the account through other means (such as through a payment from the consumer's asset account to the card issuer or from another credit account provided by the card issuer). For example:

i. Assume that, under the terms of a credit card account, a consumer is required to pay $120 in fees for the issuance or availability of credit at account opening. The consumer is also required to pay a cash advance fee that is equal to five percent of the cash advance and a late payment fee of $15 if the required minimum periodic payment is not received by the payment due date (which is the twenty-fifth of the month). At account opening on January 1 of year one, the credit limit for the account is $500. Section 1026.52(a)(1) permits the card issuer to charge to the account the $120 in fees for the issuance or availability of credit at account opening. On February 1 of year one, the consumer uses the account for a $100 cash advance. Section 1026.52(a)(1) permits the card issuer to charge a $5 cash-advance fee to the account. On March 26 of year one, the card issuer has not received the consumer's required minimum periodic payment. Section 1026.52(a)(2) permits the card issuer to charge a $15 late payment fee to the account. On July 15 of year one, the consumer uses the account for a $50 cash advance. Section 1026.52(a)(1) does not permit the card issuer to charge a $2.50 cash advance fee to the account. Furthermore, § 1026.52(a)(1) prohibits the card issuer from collecting the $2.50 cash advance fee from the consumer by other means.

[20] 15 U.S.C. 1601 *et seq.*

[21] *See* 75 FR 7791 for the Board's burden analysis under the Paperwork Reduction Act.

ii. Assume that, under the terms of a credit card account, a consumer is required to pay $125 in fees for the issuance or availability of credit during the first year after account opening. At account opening on January 1 of year one, the credit limit for the account is $500. Section 1026.52(a)(1) permits the card issuer to charge the $125 in fees to the account. However, § 1026.52(a)(1) prohibits the card issuer from requiring the consumer to make payments to the card issuer for additional non-exempt fees with respect to the account [prior to account opening or] during the first year after account opening. Section 1026.52(a)(1) also prohibits the card issuer from requiring the consumer to open a separate credit account with the card issuer to fund the payment of additional non-exempt fees [prior to the opening of the credit card account or] during the first year after the credit card account is opened.

[iii. Assume that, on January 1 of year one, a consumer is required to pay a $100 fee in order to apply for a credit card account. On January 5, the card issuer approves the consumer's application, assigns the account a credit limit of $1,000, and provides the consumer with account-opening disclosures consistent with § 1026.6. The date on which the account may first be used by the consumer to engage in transactions is January 5. The consumer is required to pay $150 in fees for the issuance or availability of credit, which § 1026.52(a)(1) permits the card issuer to charge to the account on January 5. However, because the $100 application fee is subject to the 25 percent limit in § 1026.52(a)(1), the card issuer is prohibited from requiring the consumer to pay any additional non-exempt fees with respect to the account until January 5 of year two.]

* * * * *

3. *Changes in credit limit during first year.*

i. *Increases in credit limit.* If a card issuer increases the credit limit during the first year after the account is opened, § 1026.52(a)(1) does not permit the card issuer to require the consumer to pay additional fees that would otherwise be prohibited (such as a fee for increasing the credit limit). For example, assume that, at account opening on January 1, the credit limit for a credit card account is $400 and the consumer is required to pay $100 in fees for the issuance or availability of credit. On July 1, the card issuer increases the credit limit for the account to $600. Section 1026.52(a)(1) does not permit the card issuer to require the consumer to pay additional fees based on the increased credit limit.

ii. *Decreases in credit limit.* If a card issuer decreases the credit limit during the first year after the account is opened, § 1026.52(a)(1) requires the card issuer to waive or remove any fees charged to the account that exceed 25 percent of the reduced credit limit or to credit the account for an amount equal to any fees the consumer was required to pay with respect to the account that exceed 25 percent of the reduced credit limit within a reasonable amount of time but no later than the end of the billing cycle following the billing cycle during which the credit limit was reduced. For example[:]►,◄

[A. Assume]► assume◄ that, at account opening on January 1, the credit limit for a credit card account is $1,000 and the consumer is required to pay $250 in fees for the issuance or availability of credit. The billing cycles for the account begin on the first day of the month and end on the last day of the month. On July 30, the card issuer decreases the credit limit for the account to $500. Section 1026.52(a)(1) requires the card issuer to waive or remove $175 in fees from the account or to credit the account for an amount equal to $175 within a reasonable amount of time but no later than August 31.

[B. Assume that, on June 25 of year one, a consumer is required to pay a $75 fee in order to apply for a credit card account. At account opening on July 1 of year one, the credit limit for the account is $500 and the consumer is required to pay $50 in fees for the issuance or availability of credit. The billing cycles for the account begin on the first day of the month and end on the last day of the month. On February 15 of year two, the card issuer decreases the credit limit for the account to $250. Section 1026.52(a)(1) requires the card issuer to waive or remove fees from the account or to credit the account for an amount equal to $62.50 within a reasonable amount of time but no later than March 31 of year two.]

* * * * *

52(a)(2) Fees not subject to limitations.

1. *Covered fees.* Except as provided in § 1026.52(a)(2), § 1026.52(a) applies to any fees or other charges that a card issuer will or may require the consumer to pay with respect to a credit card account [prior to account opening and] during the first year after account opening, other than charges attributable to periodic interest rates. For example, § 1026.52(a) applies to:

i. Fees that the consumer is required to pay for the issuance or availability of credit described in § 1026.60(b)(2), including any fee based on account activity or inactivity and any fee that a consumer is required to pay in order to receive a particular credit limit;

ii. Fees for insurance described in § 1026.4(b)(7) or debt cancellation or debt suspension coverage described in § 1026.4(b)(10) written in connection with a credit transaction, if the insurance or debt cancellation or debt suspension coverage is required by the terms of the account;

iii. Fees that the consumer is required to pay in order to engage in transactions using the account (such as cash advance fees, balance transfer fees, foreign transaction fees, and fees for using the account for purchases);

iv. Fees that the consumer is required to pay for violating the terms of the account (except to the extent specifically excluded by § 1026.52(a)(2)(i));

v. Fixed finance charges; and

vi. Minimum charges imposed if a charge would otherwise have been determined by applying a periodic interest rate to a balance except for the fact that such charge is smaller than the minimum.

* * * * *

Dated: April 4, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012–8534 Filed 4–11–12; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

Revisions of Boundaries for the Thunder Bay National Marine Sanctuary and Underwater Preserve; Intent To Prepare Draft Environmental Impact Statement; Scoping Meetings

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of intent to revise boundaries; intent to prepare environmental impact statement; scoping meetings.

SUMMARY: In accordance with section 304(e) of the National Marine Sanctuaries Act, as amended, (NMSA) (16 U.S.C. 1431 *et seq.*), the Office of National Marine Sanctuaries (ONMS) of the National Oceanic and Atmospheric

Administration (NOAA) has initiated a review of the Thunder Bay National Marine Sanctuary and Underwater Preserve (TBNMS or sanctuary) boundaries, to evaluate the opportunity and effects of expanding the sanctuary's boundary. The process required by NMSA will be conducted concurrently with a public process under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). This notice also informs the public that NOAA will coordinate its responsibilities under section 106 of the National Historic Preservation Act (NHPA, 16 U.S.C. 470) with its ongoing NEPA process, pursuant to 36 CFR 800.8(a) including the use of NEPA documents and public and stakeholder meetings to also meet the requirements of section 106. NOAA anticipates completion of the final environmental impact statement and concomitant documents will require approximately twelve months from the date of publication of this notice of intent.

DATES: Comments must be received by May 25, 2012. Dates for scoping meetings are:

1. April 17, 2012.
2. April 18, 2012.
3. April 19, 2012.

ADDRESSES: Comments may be submitted by any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Submit electronic comments via the Federal eRulemaking Portal with Docket Number NOAA–NOS–2012–0077.
- *Mail:* Jeff Gray, Sanctuary Superintendent, Thunder Bay National Marine Sanctuary, 500 West Fletcher Street, Alpena, MI 49707.

Instructions

All comments received are a part of the public record. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NOAA will accept anonymous comments (enter N/A in the required fields to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Ellen Brody, Great Lakes Regional Coordinator, Telephone: (734) 741–2270.

SUPPLEMENTARY INFORMATION:

Background Information

In 2000, NOAA designated the 448-square-mile Thunder Bay National Marine Sanctuary (TBNMS or sanctuary), which is jointly managed by NOAA and the State of Michigan (65 FR 39041). The sanctuary's mission is to preserve nationally significant shipwrecks and other maritime heritage resources through resource protection, education, and research. Well-preserved by Lake Huron's cold, fresh water, these shipwrecks span a century and a half of Great Lakes maritime history and include virtually all types of vessels used on the Great Lakes. Within the existing sanctuary boundary are approximately one hundred shipwrecks.

NOAA has received a number of comments expressing interest in expanding the sanctuary's boundary to include the waters adjacent to Alcona and Presque Isle Counties since the scoping process in 2006 for the sanctuary's management plan review. Several local government and non-governmental organizations passed resolutions or submitted written letters of support for boundary expansion (see *www.thunderbay.noaa.gov/management/mpr/boundexp* for copies of those documents). In 2007, the Thunder Bay Sanctuary Advisory Council adopted a resolution to increase the boundary to include Alcona, Alpena, and Presque Isle Counties to the international border with Canada to provide protection for those known maritime heritage resources and those yet to be discovered. The expanded sanctuary could include all or part of a study area proposed by the Thunder Bay Sanctuary Advisory Council. The study area for possible expansion contains approximately one hundred shipwrecks. Among them are a number of historically, archaeologically, and recreationally significant shipwrecks not currently included in the sanctuary.

The sanctuary's final management plan (2009) included the following strategy: ''Evaluate and assess a proposed expansion of the sanctuary to a 3,662-square-mile area from Alcona County to Presque Isle County, east to the international border with Canada to protect, manage, and interpret additional shipwrecks and other potential maritime heritage resources.''

In accordance with Section 304(e) of the National Marine Sanctuaries Act, as amended (NMSA), 16 U.S.C. 1431 *et seq.,* the Office of National Marine Sanctuaries (ONMS) of the National Oceanic and Atmospheric Administration (NOAA) is initiating a review of the Thunder Bay National Marine Sanctuary boundaries to ''evaluate and assess a proposed expansion'' for the sanctuary. Expanding the sanctuary boundary to include some of the best preserved shipwrecks in the Great Lakes would provide protection to maritime heritage resources under the NMSA. Designation as a sanctuary draws public attention to the fact that these cultural resources have national significance and inclusion in the national marine sanctuary system could provide additional opportunities for tourism and economic growth.

Review Process

The review process is composed of four primary stages:

1. Information collection and characterization, including public scoping meetings;
2. Preparation and release of a draft environmental impact statement (DEIS) as required by Section 304(a) of the NMSA that identifies boundary expansion alternatives, as well as a notice of proposed rulemaking (NPRM) to amend the sanctuary regulations to reflect any new boundary if proposed.
3. Public review and comment on the DEIS and NPRM; and
4. Preparation and release of a final environmental impact statement, including a response to public comments, with a final rule if appropriate.

NOAA anticipates that the completion of the final environmental impact statement and concomitant documents will require approximately twelve months.

At this time, NOAA is opening a public comment period to:

1. Gather information and public comments from individuals, organizations, and government agencies on whether TBNMS should expand its boundary, suggestions for the extent of an expanded boundary, and the potential effects of a boundary expansion;
2. Help determine the scope of issues to be addressed in the preparation of an environmental impact statement (EIS) pursuant to the National Environmental Policy Act (NEPA) (43 U.S.C. 4321 *et seq.*), if warranted; and
3. Conduct a series of public scoping meetings to collect public comment. The public scoping meeting schedule is presented below.

Public Scoping Meetings: The public scoping meetings will be held on the following dates and at the following locations beginning at 5:30 p.m. unless otherwise noted:

1. Alpena, MI

Date: April 17, 2012.

Location: Michigan Great Lakes Maritime Heritage Center.

Address: 500 W. Fletcher Street, Alpena, MI 49707.

2. Rogers City, MI

Date: April 18, 2012.

Location: Presque Isle District Library.

Address: 181 East Erie Street, Roger City, MI 49779.

3. Harrisville, MI

Date: April 19, 2012.

Location: Alcona County EMS Building.

Address: 2600 E. M–72, Harrisville, MI 48740.

Consultation Under National Historic Preservation Act

This notice confirms that NOAA will fulfill its responsibility under section 106 of the National Historic Preservation Act (NHPA, 16 U.S.C. 470) through the ongoing NEPA process, pursuant to 36 CFR 800.8(a) including the use of NEPA documents and public and stakeholder meetings to meet the section 106 requirements. The NHPA specifically applies to any agency undertaking that may affect historic properties. Pursuant to 36 CFR 800.16(1)(1), historic properties includes: ''Any prehistoric or historic district, site, building, structure or object included in, or eligible for inclusion in, the National Register of Historic Places maintained by the Secretary of the Interior. The term includes artifacts, records, and remains that are related to and located within such properties. The term includes properties of traditional religious and cultural importance to an Indian tribe or Native Hawaiian organization and that meet the National Register criteria.''

In fulfilling its responsibility under the NHPA and NEPA, NOAA intends to identify consulting parties; identify historic properties and assess the effects of the undertaking on such properties; initiate formal consultation with the State Historic Preservation Officer, the Advisory Council of Historic Preservation, and other consulting parties; involve the public in accordance with NOAA's NEPA procedures, and develop in consultation with identified consulting parties alternatives and proposed measures that might avoid, minimize or mitigate any adverse effects on historic properties and describe them in any environmental assessment or draft environmental impact statement.

Authority: 16 U.S.C. 1431 *et seq.;* 16 U.S.C. 470.

Dated: April 3, 2012.

Daniel J. Basta,

Director for the Office of National Marine Sanctuaries.

[FR Doc. 2012–8831 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 200

[Docket No. FR–5444–P–01]

RIN 2502–AJ09

Federal Housing Administration (FHA): Multifamily Accelerated Processing—Enhancing and Strengthening Multifamily Accelerated Processing

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: Multifamily Accelerated Processing (MAP) is a processing system introduced in 2000 as a pilot program to facilitate the accelerated processing of loan applications for FHA multifamily mortgage insurance, which generally involve the refinance, purchase, new construction, or rehabilitation of multifamily properties. These transactions are costly, complicated, and time-consuming to process. Prior to MAP, HUD field offices were encouraged to develop and test individual fast-track processing systems for use by qualified FHA-approved lenders that were experienced in processing loan applications for multifamily mortgages. The intent was to considerably reduce the processing time of applications. These test procedures included providing qualified lenders with the option of preparing FHA forms and undertaking preliminary underwriting for certain types of loan applications. Fast-track processing procedures developed by individual HUD offices that facilitated processing applications without sacrificing quality or increasing risk were consolidated into a national test of fast-track style processing of multifamily mortgage insurance applications under the name ''MAP.'' MAP has been administered to date through direct instructions to FHA-approved lenders under a MAP Guide. Given its experience to date with MAP, HUD believes the MAP accelerated processing procedures have been successful. To ensure the continued quality and efficiency of MAP procedures, HUD is codifying in regulations key provisions of MAP and introducing new provisions to strengthen MAP, to assure the integrity and competency of FHA-approved lenders as directed by the Helping Families Save Their Homes Act of 2009.

DATES: *Comment Due Date:* June 11, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–

8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Terry W. Clark, Office of Multifamily Development, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6134, Washington, DC 20410; telephone number 202–402–2663 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

A. MAP

The purpose of MAP is to have in place an accelerated system for processing FHA multifamily mortgage insurance applications that is consistent at each HUD multifamily processing office, and that significantly reduces the amount of time that HUD staff spends reviewing those applications. Under MAP, the lender is responsible for preparation of most of the application exhibits, such as the appraisal, and for making a recommendation to HUD based upon the lender's processing and underwriting. This results in a considerable time savings for the lender. For example, under MAP, FHA-approved lenders are provided an earlier review of the application for insurance on new construction and substantial rehabilitation. Therefore, if the application is rejected at a pre-application stage, the lender and borrower do not spend the time and money required to prepare the more extensive exhibits and analysis for the application for an FHA firm commitment. While considerable responsibility for preparation of documents and initial review is placed with the lender, FHA still reviews a lender's exhibits and makes the final underwriting decision.

MAP is not automatically available to all FHA-approved lenders. To use MAP, an FHA-approved lender must apply for approval and be approved as a MAP lender by HUD's Office of Multifamily Housing Development, Lender Qualification and Monitoring Division (LQMD). The appraisers and MAP-approved underwriters of the FHA-approved lender seeking MAP-lender designation must also attend a MAP training session. Lenders that are approved as MAP lenders are determined by HUD to be skilled in underwriting multifamily housing loans and in the preparation of applications for FHA multifamily mortgage insurance. Approval is on a nationwide basis; consequently, the MAP lender may submit applications using MAP regardless of where the property is located or which Multifamily Hub or Program Center will be processing the loan. As a condition of the opportunity to use MAP, a MAP lender's MAP loans are subject to post-endorsement review by LQMD. MAP-lender approval will be for a defined period, and may be renewed, denied renewal, or terminated by FHA as provided in this proposed rule. For example, if the MAP lender fails to meet HUD standards for underwriting loans, its MAP designation also may be terminated.

Under the current MAP system, MAP may be used for the following FHA-insured multifamily programs: Section 220 (apartments in urban renewal areas), Sections 221(d)(3) and 221(d)(4) (apartments), Section 223(a)(7) (refinance of existing insured properties), Section 223(f) (acquisition or refinancing of existing apartments), and Section 231 (housing for the elderly) new construction or substantial rehabilitation. MAP may be used for such other FHA-insured multifamily programs as may be announced by FHA.

From the outset, through MAP, FHA has strived to strike a careful balance between expedited processing and ensuring an acceptable level of risk for HUD's multifamily mortgage insurance programs. Based on HUD's experience to date with MAP, this proposed rule strives not only to maintain that balance but to enhance the quality, competency, and integrity of FHA-approved lenders that are approved as MAP lenders and to manage risk to a level that is acceptable to FHA.

B. MAP Today

The MAP program has changed significantly in recent years. Since its commencement in 2000, there are now more than 100 FHA-approved MAP lenders. Multifamily loan volume has increased seven-fold, while the number of HUD multifamily housing staff has declined. Transactions are larger and more complex than in the past, and mixed-use projects with commercial components are more common. Most projects have market rents and fewer than in the past are supported by rental assistance. The insured portfolio is growing quickly, but with some concentrations in markets that have experienced soft or deteriorating conditions, and with repeat borrowers in some markets. MAP is increasingly used for affordable housing construction and preservation projects with tax credits and other subsidies, and these transactions require special expertise to process.

C. Strengthening the Quality of FHA-Approved Lenders and Underwriters

Part of the impetus to review the MAP system, particularly the qualifications of an FHA-approved lender to engage in MAP, and to codify lender qualifications and the core requirements of MAP, is the Helping Families Save Their Homes Act of 2009 (HFSH Act). The HFSH Act (Division A of Pub. L. 111–22, approved May 20, 2009), among other things, directs FHA to strengthen the existing FHA lender approval process, including by ensuring that only lenders of integrity are approved by FHA as approved mortgagees.

FHA responded to this statutory direction by taking several steps. Shortly following enactment of the HFSH Act, FHA issued Mortgagee Letter 2009–31, entitled ''Strengthening Counterparty Risk Management,'' which advised FHA-lenders of the additional ineligibility criteria established by the HFSH Act, and the immediate applicability of such criteria. FHA also issued Mortgagee Letter 2009–41, which addressed Appraisal Performance Standards and Sanctions, and that reminded FHA-approved lenders of their responsibility, along with the appraisers, for the quality and accuracy of appraisals. By final rule issued on April 20, 2010 (75 FR 20718), FHA increased the net worth requirements of FHA-approved lenders, both single family and multifamily lenders. These increases were the first since 1993, and were adopted to ensure that FHA-approved lenders are sufficiently capitalized for the financial transactions occurring, and the concomitant risks present, in today's economy. On May 2, 2011, at 76 FR 24507, FHA announced the update of 36 multifamily rental project loan-closing documents, the majority of which had not been updated in more than two decades. The updated closing documents reflected the greater flexibility provided to lenders to address problems that arise in management of the property, but also greater responsibility to undertake increased due diligence to assure sound underwriting in insured multifamily projects.

All these steps that have been taken are directed to raising the level of competency and integrity of participating lenders, and ensuring the continued viability and availability of FHA mortgage insurance programs. This proposed rule, which addresses the MAP system, is another such step to strengthen FHA, its programs, and participants, and is consistent with recent Congressional direction for FHA to focus on minimize risk in its multifamily housing programs. In the Senate Committee Report that accompanied the Senate bill, S.1596, which provides Fiscal Year (FY) 2012 appropriations for HUD, the Committee noted that as a result of the housing crisis, the demand for FHA multifamily housing loans has increased, and stated: ''In an effort to respond to this increased demand, HUD is streamlining its multifamily processes and updating its programs to address current market conditions. The Committee also expects FHA to increase its attention to the additional risk this volume brings, and expects FHA to dedicate the same level of attention to risks in the multifamily program as it has to risks in its single family program.'' (See Senate Report 113–83, issued September 21, 2011, at page 135.) The changes proposed by this rule, as discussed in the following sections of this preamble, will not only improve the MAP system, by increasing efficiency in the system, but also reduce risk to FHA.

II. This Proposed Rule

This rule proposes to establish codified regulations for lender and underwriter eligibility and tier qualification criteria for MAP participation, and for FHA's process for approving MAP lenders and underwriters. Currently, HUD's MAP regulations, codified in 24 CFR part 200, subpart Y, address only the enforcement actions that FHA may take against a MAP lender. As the following discussion will highlight, enforcement actions remain a key part of the regulations, but HUD proposes, through this rule, to add new provisions to 24 CFR part 200, subpart Y, to provide for a tiered approval system, the periodic expiration of approval, and lender application for reapproval under the MAP system.

New regulatory section, § 200.1401, entitled ''Purpose of MAP and this Subpart,'' reflects the broader scope of the MAP regulations as proposed to be revised to this rule, and new section § 200.1403, the definition section, defines terms used in the proposed revised regulations. New regulatory section, § 200.1407, sets out the responsibilities of the MAP lender. These responsibilities reflect the obligation of the MAP lender to not only ensure the skill and competency of the lender's principal staff members, but to also ensure that the MAP lender is operating with the integrity contemplated by the HFSH Act.

A. Tiered MAP Lender and Underwriter Approval

The MAP approval tiers, set out in § 200.1411(b) and § 200.1413(b), are based on HUD's experience in administering the MAP program, which has shown that the most difficult programs to underwrite are those for new construction and substantial rehabilitation or that involve various sources of government assistance. HUD recognizes that all MAP lenders and underwriters do not necessarily have the skills and experience to competently handle all the MAP programs. Tiered approval will assure that MAP programs with greater underwriting demands and higher risk will require participants to have greater expertise. Both new and existing lenders and underwriters must comply with tier requirements to submit an application under MAP and must be approved by tier based upon meeting the tier qualifications. Section 200.1413 of the proposed rule set outs the lender eligibility and application process for MAP approval.

Section 200.1415 of the proposed rule establishes the MAP eligibility and application approval process for underwriters. The addition of a separate MAP eligibility and approval process for underwriters underscores the significance of having an experienced and skilled underwriter for MAP processing. Consistent with § 200.1415 concerning underwriter eligibility, § 200.1425 provides for post-approval training for underwriters, and § 200.1427 provides that HUD may terminate the approval of an underwriter that has not submitted a pre-application or application for Firm Commitment for a period of 2 years.

The tier approval designation for which MAP lenders and underwriters will be approved will be based on their multifamily transaction experience, as evidenced by recently closed loans and each loan's performance. As provided in § 200.1411(b), HUD will establish four approval tiers:

Tier 1: Market-rate refinancing under Section 223(f) or 223(a)(7);

Tier 2: Refinancing under Section 223(f) or Section 223(a)(7) of affordable housing properties with government subsidies;

Tier 3: Market-rate new construction or substantial rehabilitation under Section 220, 221(d), 231 or 241;

Tier 4: New construction or substantial rehabilitation under Sections 220, 221(d), 231, or 241 of affordable housing properties with government subsidies. Government subsidies refer to such programs as the Low-Income Housing Tax Credit (LIHTC) program, tax-exempt bond financing, HUD's Section 8 Project-Based Rental Assistance program, and HUD's Section 236 Interest Reduction Payments and similar forms of rental subsidy for affordable housing.

As provided in the accompanying notice, published elsewhere in today's **Federal Register**, HUD will from time to time issue the quantity, specific characteristics, and recentness of transactions that a lender or underwriter must have underwritten in order to have the adequate recent experience required for each tier. Each issuance will be preceded by notice and the opportunity for public comment. The relevant lending experience that HUD will recognize need not be exclusively with FHA programs, but may also be with those of Fannie Mae, Freddie Mac, state housing finance agencies, conventional lenders, or commercial banks. Non-FHA loan program experience must be equivalent to the programs offered under MAP and to the underwriting functions required under MAP, to be given credit. For current MAP lenders and underwriters, relevant lending activity involving MAP programs will be given the most weight. Consistent with HUD's commitment to notify MAP lenders or prospective MAP lenders of changes to the requisite experience needed, § 200.1417(a)(1)(iii) provides for HUD to limit the size of a loan that an approved MAP lender may process, with such limitation established either by the number of units for which a loan can be made or by the dollar amount of the loan. Although an applicant may meet the criteria for approval as a MAP lender at a requested tier or at a lower tier, HUD may decide, based on the applicant's MAP application and experience to date, or based on the conditions of the housing market at the time, that limitations should be placed on the size of loans processed by a MAP lender or lenders.

With respect to tier approval, § 200.1423 permits an approved MAP lender or underwriter to submit an application at any time requesting approval at a higher tier than originally assigned to the MAP lender or underwriter. In determining whether the MAP lender or underwriter meets the criteria for a higher tier, HUD will follow the procedures in §§ 200.1413, 200.1415, and 200.1417.

B. Periodic Renewal of MAP Lender Approval

A key goal of this proposed rule is to assure a high level of quality and integrity of FHA-approved lenders that are approved to be MAP lenders. As provided in § 200.1407, a MAP-approved lender is given considerable authority and responsibility in the processing of multifamily mortgage transactions. Given the trust and responsibility that FHA places in these lenders, it is important for FHA to ensure that these lenders, not only at the time of initial MAP lender approval but throughout the lenders' tenure as MAP lenders, remain lenders of competency and integrity, and are up-to-date on changes in multifamily transactions and skilled and experienced in underwriting and processing loan applications for these transactions. The expiration of MAP lender approval and the requirement to apply periodically for renewal of MAP-approval designation will help ensure that MAP lenders remain competent to fast-track multifamily mortgage insurance applications through the MAP system.

Currently, MAP approval designation does not expire unless there is an enforcement action that results in termination, or there is an eligibility requirement that the FHA-approved lender no longer meets. As provided in § 200.1417(b), this rule proposes to change the existing MAP system by requiring MAP approved lenders to apply to renew their approval every 4 years. At such time, the MAP lender's performance will be reviewed and FHA will determine whether the MAP-approval designation should be renewed. This proposed rule provides in § 200.1421, that no later than 90 days before the date of the end of the 4-year period of a MAP lender's approval, the MAP lender must reapply for approval. The requirement to renew MAP-lender designation allows FHA to assess the lender's 4-year performance as a MAP lender, and determine whether the FHA-approved lender's designation as a MAP lender should be renewed or disapproved, and if it should be renewed at the tier for which the FHA-approved lender was previously approved or at a lower tier, if so warranted.

For example, FHA may determine that the MAP lender's experience during the preceding 4 years is not sufficient or at a level of performance for the FHA-approved MAP lender to maintain its current tier approval; however, the FHA-approved MAP lender can be renewed under a lower tier at which its performance has been satisfactory. The proposed period for MAP approval is based on HUD's experience that MAP lenders' performance, underwriting practices, and business processes typically evolve over time as changes in personnel, management, and market conditions occur. As a result, the capacity of the institution may be markedly different from when it was originally approved and assigned to a tier by HUD. HUD has determined that a 4 year approval period appropriately balances the need to protect the FHA insurance fund with HUD's desire to minimize inconvenience to lenders. Upon application for renewal, the lender's record, including any sanctions or enforcement actions taken against the lender, its default and claim rates, and the overall performance of its underwritten or closed loans will be taken into account when determining whether MAP approval should be renewed or disapproved. Although a lender's initial and ongoing MAP approval period will normally be for 4 years, the term of approval may be shorter based upon a review of the lender's application and record.

C. Conditional MAP Approval and Expiration of Existing MAP Approvals

The proposed rule provides, in § 200.1417(b)(3), that FHA may also grant conditional MAP lender or underwriter approval if the lender or underwriter lacks experience in processing or underwriting FHA loan applications. If the lender or underwriter satisfies the conditions imposed by FHA, for example, by undertaking additional training within a specified period of time or completing a predetermined number of acceptably underwritten closings, then full approval may be granted upon completion of the condition. Conditional approval, however, will not be indefinite. FHA will impose a deadline for the completion of the conditions for which full approval is necessary, usually one year from the date on which conditional approval is granted. Conditional approval may be granted for initial MAP approval, or may be granted in cases where a currently approved MAP lender requests an upgrade in tier approval.

The proposed rule provides, in § 200.1419, that MAP lender and underwriter approvals issued prior to the effective date of the final rule under this rulemaking will expire 45 days following the lender's or underwriter's receipt of a letter from HUD inviting the lender or underwriter to apply for tier approval. HUD anticipates that it will send such letters to approximately 25 percent of lenders and underwriters with existing approvals per year, for 4 years, and that this pace may vary depending upon HUD's resources for processing applications. If the lender or underwriter submits a timely application for tier approval, the existing approval will continue to be valid until HUD notifies the applicant of the action it is taking on the application for tier approval. A lender or underwriter that fails to respond in a timely manner to the letter will be eligible for approval at Tier 1 for a period of time as provided for conditional approvals in § 200.1417(b).

D. Other Provisions of the Proposed Rule

Additional New Regulatory Sections

In addition to the new sections discussed above in this preamble, new § 200.1405 addresses the multifamily programs eligible for MAP processing, which will be posted on HUD's Web site; such postings will ensure that the most up-to-date list of eligible MAP multifamily programs is available to the public. As noted earlier, § 200.1407 lists the responsibilities of a MAP lender. As also noted earlier, § 200.1413(b) addresses the tier-specific criteria that lenders must meet. Paragraph (a) of this section, § 200.1413(a), addresses the general requirements for MAP-lender approval. Section 200.1419 addresses appeals, and provides that an applicant may submit a written appeal of any HUD decision regarding the applicant under §§ 200.1411 through 200.1427. This section provides that the appeal must be submitted to HUD within 30 days of the date of the applicant's receipt of HUD's written notification to the applicant of its decision. This section also provides that HUD will respond to the applicant's appeal within 60 days of HUD's receipt of the applicant's appeal, and that if HUD's appeal decision confirms HUD's original decision, no further appeals will be accepted.

Existing Regulatory Sections

As noted earlier in this preamble, this proposed rule builds upon the existing regulations in 24 CFR part 200, subpart Y, which currently address MAP enforcement and sanctions. The enforcement provisions remain in place with certain organization revisions. For example, the proposed rule would eliminate provisions vesting existing authorities to undertake certain enforcement and corrective actions against MAP lenders and underwriters in a MAP Lender Review Board. HUD has found that it is unnecessary to create and maintain such a board because it is duplicative of other offices within HUD, such as the Lender Qualifications and Monitoring Division that are responsible for monitoring and ensuring compliance with MAP requirements. This change would not alter the existing authorities to take such actions, nor the procedural protections, including notice and opportunity to be heard, that are provided in § 200.1535. Rather, it would merely revise provisions that currently specify that it is the MAP Lender Review Board that is vested with the authorities. Accordingly, existing references to the MAP Lender Review Board in 24 CFR part 200, subpart Y, would be replaced simply with references to HUD. HUD would specify the office or official that would carry out these functions through its ordinary delegations process. At the final rule stage, HUD will include amendatory instructions that will make a nomenclature change throughout subpart Y to substitute ''HUD'' wherever the terms ''the MAP Lender Review Board'' and ''Board'' appear.

E. Proposed MAP Rule—Increasing Efficiency and Reducing Burden

Since its inception, MAP has been shown to increase efficiency in processing multifamily mortgage applications without increasing risk to FHA. Under the current structure, an approved lender or underwriter can originate any qualifying multifamily mortgage. This rule proposes to further increase efficiency by approving lenders and underwriters for one of four tiers based on their origination experience.

The primary benefit of changes proposed by this rule is to further increase the efficiency and processing of multifamily mortgage applications. The tiered structure will decrease the number of rejected applications, reducing time spent by lenders and FHA staff in reviewing applications. This change will be accomplished by better aligning lenders and underwriters with the programs with which they are most experienced. FHA does not expect a change in volume of their multifamily originations as a result of the creation of tiers within the MAP program or a significant shift of business between lenders within MAP. Instead, HUD expects that the number of unsuccessful applications will decrease.

In FY 2011, approximately 230 multifamily mortgage applications were not approved. FHA staff spent approximately 400 hours processing MAP mortgage applications. The Bureau of Labor Statistics reports almost $40 per hour as the median wage for government employees in financial operations. Meanwhile, lenders spent about 450 hours of staff time preparing applications for new construction or substantial rehabilitation and approximately 300 hours of staff time on mortgage applications for refinance. Based on HUD's knowledge of the industry, the hourly rate for staff preparing applications is approximately $75. If implementation of the changes proposed by this rule is successful in eliminating 75 percent of these unapproved applications, FHA would save $2.772 million in staff time and lenders would save $5.003 million in staff time. In sum, this proposed rule can be expected to produce benefits totaling $7.775 million.

TABLE 1—AVOIDED STAFF TIME PREPARING UNSUCCESSFUL MORTGAGE APPLICATIONS

	Number of applications *	Hours per response	Hourly cost	Total annual cost
FHA:				
New Construction/Substantial Rehabilitation	98	400	$40	$1,572,000
Refinance	75	400	40	1,200,000
FHA Subtotal				2,772,000
Lenders:				
New Construction/Substantial Rehabilition	98	450	75	3,315,938
Refinance	75	300	75	1,687,500
Lender Subtotal				5,003,478
Total Costs				7,775,489

* Number of Applications is approximately 75 percent of the number of unapproved MAP mortgage applications in FY 2011.

In addition to creating tiers, this rule proposes to require renewal as a MAP lender every 4 years.[1] This new requirement will increase costs to participating lenders as additional staff time will be spent preparing the MAP renewal application. There are currently 92 approved MAP lenders. FHA estimates that lenders spend about 40 hours preparing documents for each MAP approval. Following the initial tier placement, lenders may subsequently decide to apply for adjustment to a higher tier (before the 4-year period ends). FHA expects about ten underwriters and five lenders to apply for adjustment to a higher tier, requiring about 20 hours per application. Finally, although FHA currently receives several appeals each year, the number could increase slightly as a lender could appeal not only a rejection but also the tier in which the lender is placed. In FY 2011, only two appeals were filed for denied applications. FHA does not expect an increase of more than three appeals annually as a result of the change to a tiered system. Preparation of each appeal by a lender or underwriter is expected to require one hour of applicant time.

Based on knowledge of industry wages, the estimated hourly wage of lenders and underwriters that prepare these types of documents is approximately $100. The table below shows the total cost estimate per category. The total cost to lenders and underwriters as a result of this rule would be $398,300.

[1] Currently approved lenders will be required to submit an application of renewal, with about one-quarter renewing annually over a 4-year period.

TABLE 2—COSTS OF RENEWAL, ADJUSTMENT, AND APPEALS

Type	Number	Hours per response	Hourly cost	Total annual cost
Lender renewal	92	40	$100	$368,000
Adjustment to Higher Tier	15	20	100	30,000
Appeals	3	1	100	300
Total Costs				398,300

As a processing system, much of the processes of MAP as the above tables reflect pertain to information collection (that is, submission of documentation to HUD and HUD review of the documentation) or recordkeeping. The MAP information collection requirements are subject to the notice and comment procedures of the Paperwork Reduction Act of 1995 (PRA). The requirements are currently approved under PRA and reflect OMB approval numbers. Consistent with the requirements of the PRA, these requirements must be published for notice and comment every 3 years. The changes that this rule would make to the current information collection requirements are set out in the table provided in the following section of the preamble, Section IV, and the public comment that this rule solicits also solicits comment on the reporting and recordkeeping burden.

III. Regulatory Review

Executive Order (EO) 13563, entitled ''Improving Regulation and Regulatory Review,'' was signed by the President on January 18, 2011, and published on January 21, 2011 (76 FR 3821). This EO requires executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Section 4 of the EO, entitled ''Flexible Approaches,'' provides, in relevant part, that where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. HUD submits that the changes proposed by this rule to the MAP system are consistent with the EO's directions. As the preceding section discussed, the changes proposed by this rule will increase efficiency in the MAP system both for HUD and MAP approved lenders.

IV. Findings and Certifications

Paperwork Reduction Act

The information collection requirements contained in this rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

The burden of the information collections in this rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Information collection	Number of respondents	Response frequency (average)	Total annual responses	Burden hours per response (in hours)	Total annual hours
§ 200.1413(c) (application for approval of tier qualification).	10 new applicants	Annually	10	40	400
§ 200.1415(b) (underwriter's application for MAP approval).	60 underwriters	Annually	60	20	1,200
§ 200.1421 (renewal of MAP lender approval).	23 lenders renewing annually	Annually	23	20	460
§ 200.1421 (adjustment of approval to a higher tier).	10 underwriters and 5 lenders applying annually.	Annually	15	20	300
§ 200.1429 (appeals)	5 appeals	Annually	5	1	5
Total	113		113	101	2,365

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this rule. Comments must refer to the proposal by name and docket number (FR–444–P–01) and must be sent to:

HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Fax: (202) 395–6947, and

Reports Liaison Officer, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 9116, Washington, DC 20410.

Interested persons may submit comments regarding the information collection requirements electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. MAP lenders consist of both small and large FHA-approved lenders that have the skill and experience to take on responsibilities that would otherwise be handled by FHA staff in the processing of applications. The system commenced as a demonstration to determine whether multifamily mortgage insurance applications could be processed on an accelerated basis without risking the quality of processing and without increasing risk to the FHA insurance fund. Overall, the MAP system has been effective, and HUD is proposing to codify, in regulation, key requirements of the MAP system.

Through this rule, HUD is proposing improved oversight of the MAP system, to meet the statutory directive that HUD ensure that only lenders of integrity are approved by FHA as FHA-approved mortgagees, and remain lenders of integrity, competency, and skill after FHA approval is granted. HUD is not proposing significant changes to participation in the MAP system. The eligibility requirements essentially remain the same, with only minor adjustment to ensure that the lenders have experience in processing the more complex transactions. However, HUD is proposing that MAP lenders have their MAP approval designation renewed every 4 years. This renewal-approval process will improve the quality of monitoring of MAP lenders by HUD, because the renewal process provides for a minimum performance review of the MAP lender by HUD every 4 years. The new requirements introduced by HUD through this proposed rule pertain to a MAP lender's performance, regardless of whether the MAP lender is small or large.

The codification of the eligibility criteria, together with HUD's oversight requirements, which are already codified, will provide a convenient location for FHA-approved lenders and other interested parties to reference the key features and requirements of the MAP system. For these reasons, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Notwithstanding HUD's determination that this rule would not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding less burdensome alternatives to this rule that would meet HUD's objectives as described in this preamble.

Environmental Impact

This rule does not direct, provide for assistance or loan and mortgage insurance or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. The rule is, therefore, categorically excluded under 24 CFR 50.19(c)(k1) and a Finding of No Significant Impact (FONSI) does not need to be prepared for this document.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of section 6 of the executive order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the executive order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1531–1538) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This rule does not impose any federal mandate on any state, local, or tribal government or the private sector within the meaning of UMRA.

List of Subjects in 24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Housing standards, Lead poisoning, Loan programs—housing and community development, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social Security, Unemployment compensation, Wages.

For the reasons stated in the preamble, HUD proposes to amend 24 CFR part 200, as follows:

PART 200—INTRODUCTION TO FHA PROGRAMS

1. The authority citation for 24 CFR part 200 continues to read as follows:

Authority: 12 U.S.C. 1702–1715z–21; 42 U.S.C. 3535(d).

2. Revise the heading of subpart Y and add §§ 200.1401, 200.1403, 200.1405, 200.1407, 200.1409, 200.1411, 200.1413, 200.1415, 200.1417, 200.1419, 200.1421, 200.1423, 200.1425, 200.1427, and 200.1429, and undesignated headings, and revise the subpart table of contents to read as follows:

Subpart Y—Multifamily Accelerated Processing (MAP): Eligibility, Approval, Quality Assurance, and Enforcement for MAP Lenders and Underwriters

General

Sec.

Approval of Lenders and Underwriters

General

§ 200.1401 Purpose of MAP and this subpart.

(a) MAP is a national accelerated processing system for the FHA multifamily mortgage insurance programs. An FHA-approved lender that is approved to process multifamily mortgage insurance applications under MAP is responsible for preparation of the majority of the exhibits involved in the processing of a multifamily mortgage insured by FHA, such as the appraisal required for an application for mortgage insurance, and for making a recommendation to HUD based upon the lender's processing and underwriting. HUD, however, reviews the lender's exhibits and makes the final underwriting decision.

(b) This subpart establishes the criteria by which a new or existing FHA-approved lender or underwriter receives and maintains MAP approval, the basic responsibilities of a MAP lender, the manner in which FHA will monitor a MAP Lender's performance, the enforcement actions that FHA may take against a MAP lender for violation of requirements, and the due process procedures available to a MAP lender. Unless superseded by the requirements of this part, the MAP processing instructions, submission, and reporting requirements issued through supplemental guidance remain applicable to the MAP system.

§ 200.1403 Definitions.

The definitions in 24 CFR 200.3 are applicable to this subpart. Additionally, as used in this subpart:

Government subsidy means one or more of the following: Low-Income Housing Tax Credits, Section 8 Project-Based Rental Assistance, Rent-restricted bond financing, Section 236 Interest Reduction Payments, and any other similar form of affordable housing subsidy, as identified by HUD.

In good standing means being in compliance with all applicable FHA and MAP requirements, not being in inactive status (in accordance with § 200.1427, as applicable), not being subject to or under consideration for MAP approval, suspension, or termination and, in the case of a lender, being approved to participate in FHA Multifamily Mortgage Insurance programs as a supervised lender or mortgagee or nonsupervised lender or mortgagee.

Principal means a primary participant of the lender entity, who is empowered to act as the lender's representative.

Principal staff members refer to those persons designated by the lender as approved MAP underwriter(s), construction loan administrator(s), and other authorized signatory(s) with authority to bind the lender on MAP loan applications.

§ 200.1405 FHA programs eligible for MAP processing.

FHA-insured multifamily programs that are eligible for processing under MAP are listed on HUD's Web site at *www.hud.gov.*

§ 200.1407 MAP lender responsibilities.

(a) A MAP lender shall comply with such processing instructions, submission, and reporting requirements through the regulations of this subpart and as may be otherwise specified by HUD through supplemental guidance.

(b) A MAP lender must submit to the HUD office, as designated by HUD, the qualifications of the MAP lender's principal staff members or consultants who will be reviewing or preparing the lender's application for mortgage loan insurance.

(c) MAP lenders must establish and maintain separation between the underwriting and origination functions to ensure that individuals performing underwriting functions do not face any incentive to approve a loan that does not meet applicable underwriting standards. Minimum standards for establishing and maintaining such separation include, but are not limited to, the following:

(1) An individual may not underwrite or participate in underwriting a loan if the individual will receive or expects to receive either directly or indirectly any compensation that is contingent upon origination of that loan;

(2) Underwriting staff are not evaluated by origination staff, and compensation of underwriting staff shall not be tied to loan production levels;

(3) Underwriters must be full-time, salaried employees of the lender and may not be independent contractors or temporary workers;

(4) Origination staff shall be precluded from hiring contractors, such as appraisers or market analysts, on behalf of underwriters; and

(5) MAP lenders shall ensure that origination staff does not have management authority over or influence on the duties or conclusions of underwriting staff.

(d)(1) A MAP lender must submit annually to HUD, in accordance with procedures specified by HUD, including, but not limited to, the requirements of 24 CFR 200.62, an update of MAP lender status, certified by an individual who is authorized to bind the MAP lender. The certified update must be submitted no later than June 30 of each year and must:

(i) List the names of the following individuals:

(A) The MAP lender's MAP-approved underwriters and the tiers at which they are approved;

(B) The MAP lender's construction loan administrators (if applicable); and

(C) Individuals who are authorized to bind the MAP lender by signing FHA mortgage insurance applications; and

(ii) State that all of the MAP lender's MAP-approved underwriters have received tier approval and have attended the training required under § 200.1425.

(2) False claims and statements may result in criminal and civil penalties pursuant to 12 U.S.C. 1735f–14, 18 U.S.C. 1001, 1010, 1012, and 31 U.S.C. 3729, 3802.

Approval of Lenders and Underwriters

§ 200.1411 Approval required.

(a) *General.* A lender may not process and an underwriter may not underwrite a loan application utilizing MAP unless:

(1) The lender is approved by and is in good standing with HUD as a MAP lender for the loan transaction for which the application is submitted; and

(2) The underwriter who will underwrite the loan and sign the underwriter's narrative is approved by and is in good standing with HUD as a MAP underwriter for that lender and for the tier designation and loan program under which the application is submitted. Approval as a MAP underwriter does not entitle an underwriter to underwrite loans for a lender other than for the MAP-approved lender that submitted the underwriter application approved by HUD. A MAP-approved lender that employs an underwriter previously approved as an underwriter for another MAP-approved lender must submit an application for underwriter approval in accordance with § 200.1415(b), and HUD will evaluate the application and take action in accordance with § 200.1417.

(b) *Tiered approval.* HUD will provide approvals and renewals of approvals of new and existing MAP lenders and underwriters on a tiered basis in accordance with a lender's or underwriter's experience and qualifications at the time of application. A MAP lender or underwriter may not use MAP to process or underwrite loan transactions that are not covered by the lender's or underwriter's approval tier (''covered loan transactions''), which are as follows:

(1) Tier 1: MAP-eligible acquisition and refinancing programs without government subsidies;

(2) Tier 2: MAP-eligible acquisition and refinancing programs with or without government subsidies;

(3) Tier 3: All MAP-eligible programs without government subsidies; and

(4) Tier 4: All MAP-eligible programs, with or without government subsidies.

(c) *Nationwide validity.* Approval as a MAP lender or underwriter, which includes approval at a particular tier, is valid for transactions nationwide, regardless of where the property that will serve as the security for the mortgage is located or which HUD office will process a transaction. Approved lenders and their approval tier will be posted on HUD's Web site, which will be regularly updated to reflect any change in the lender's tier or MAP-approval status.

§ 200.1413 Lender eligibility and application for MAP approval.

To be eligible for designation as a MAP lender, a lender must meet the general requirements under paragraph (a) of this section and the applicable tier-specific requirements under paragraph (b) of this section. HUD will not approve the application of a lender that does not meet the Tier 1 requirements.

(a) *General requirements.* The lender:

(1) Must be approved as an FHA-approved lender under parts 202 of this chapter;

(2) Must not be subject to judgments arising from lawsuits or administrative proceedings that would adversely impact its ability to conduct business as a lender, or subject to any of the ineligibility criteria specified in 24 CFR 202.5(j); and

(3) Must have an employee who is approved by HUD as a MAP underwriter. Application for the qualifying MAP underwriter approval may be submitted prior to or simultaneously with a lender's application for MAP-lender approval.

(b) *Tier-specific requirements.* For a lender to obtain approval at a specific tier:

(1) The lender must have adequate capacity and experience in processing and in underwriting covered loan transactions for that tier using FHA insurance programs, or non-FHA transactions that are equivalent to covered transactions for that tier.

(i) A non-FHA transaction will be deemed the equivalent of using FHA insurance programs for a covered transaction for a tier if HUD determines that the quality and scope of underwriting and processing required and actually performed for the non-FHA transaction are equivalent to that required using FHA insurance programs for the covered transaction. Non-FHA transactions that may be used to demonstrate tier qualifications include those of Fannie Mae, Freddie Mac, state housing finance agencies, conventional lenders, and commercial banks;

(ii) HUD will from time to time issue the quantity, specific characteristics, and recentness of transactions that a lender must have processed or underwritten in order to have the adequate recent experience required for each tier. Each issuance will be preceded by notice and the opportunity for public comment.

(2) The lender must have a satisfactory record processing and underwriting covered transactions for the tier at which approval is requested. In reviewing the lender's record, HUD will consider enforcement actions taken against the lender, warning letters issued to the lender, the lender's default and claim rates, and the overall performance of its previously underwritten or closed loans.

(c) *Application.* (1) The lender must submit an application for MAP approval or for tier qualification in such form as required by HUD, demonstrating that the lender meets the applicable eligibility requirements under this section.

(2) HUD may from time to time announce its suspension of acceptance of applications under this section. The announcement shall specify the reasons for the suspension of acceptance of applications.

(3) An FHA-approved lender that has had its MAP lender designation terminated may not submit an application for MAP lender designation for a period of one year following the date of termination of the prior MAP lender designation.

§ 200.1415 Underwriter eligibility and application for MAP approval.

(a) To be eligible for designation as a MAP underwriter, an individual must be a full-time employee of the lender that is seeking or has received approval as a MAP Lender, and must have adequate experience in underwriting covered loan transactions using FHA insurance programs for the specific tier for which the underwriter seeks designation, or non-FHA transactions that are equivalent to covered transactions for that tier.

(1) A non-FHA transaction will be deemed the equivalent of using FHA insurance programs for a covered transaction for a tier if HUD determines that the quality and scope of underwriting and processing required and actually performed for the non-FHA transaction are equivalent to that required using FHA insurance programs for the covered transaction. Non-FHA transactions that may be used to demonstrate tier qualifications include those of Fannie Mae, Freddie Mac, state housing finance agencies, conventional lenders, and commercial banks.

(2) HUD will from time to time issue the quantity, specific characteristics, and recentness of transactions that an underwriter must have underwritten in order to have the adequate recent experience required for each tier. Each issuance will be preceded by notice and the opportunity for public comment.

(b) A lender must submit an underwriter's application for MAP-underwriter approval or for underwriter-tier qualification in such form as required by HUD that demonstrates that the underwriter meets the applicable eligibility requirements under this section.

§ 200.1417 HUD's review of MAP lender and underwriter approval applications.

(a) HUD will review a MAP lender or underwriter approval application, along with any information from HUD offices where the applicant's prior loan applications or exhibits have been submitted within the preceding time period specified by HUD.

(1)(i) If HUD determines that the applicant meets the criteria for approval in § 200.1413 or § 200.1415, as applicable, the applicant is eligible for approval for the requested tier and HUD will notify the applicant of its decision to designate the lender or underwriter as a MAP lender or underwriter under the tier for which the lender or underwriter applied.

(ii) If HUD determines that the applicant does not meet the criteria for the requested tier but the applicant meets the criteria for approval at a lower tier, HUD may approve the application at the lower tier. In such a case, HUD will notify the applicant of its eligibility for approval at a lower tier and advise the applicant of the reasons that HUD did not approve the applicant at the requested tier.

(iii) Whether HUD approves an applicant at a requested tier under paragraph (a)(1)(i) of this section or at a lower tier under paragraph (a)(1)(ii) of this section, HUD reserves the right to limit the number of units or the dollar amount per loan application that an approved applicant may process, when HUD determines that there is a necessity to limit the loans being processed to such amount or size, as HUD may specify by notice.

(2) If HUD determines that the applicant does not meet the criteria for approval in § 200.1413 or § 200.1415, as applicable, HUD will disapprove the application and notify the applicant of its decision and of the reason for the disapproval.

(3) If HUD is unable to determine the eligibility of an applicant, HUD may, at its discretion, disapprove the application and notify the applicant of the reason for its decision or ask the applicant to correct identified deficiencies in the application and resubmit it.

(b) *Period of approval.* Unless an approval is affected by an enforcement action under this part, an approval granted under this section shall be valid, as follows:

(1) Except as provided under paragraph (b)(3) of this section and under § 200.1427, the approval of an underwriter will not expire so long as the underwriter remains active and in the employment of the lender under which approval was granted, and without interruption.

(2) Except as provided in paragraphs (b)(3) of this section, or for reasons otherwise specified by HUD in writing, the approval of a lender as a MAP lender is valid for a period of 4 years from the date on which HUD notifies the lender of the approval;

(3)(i) A lender or underwriter without prior experience in processing or underwriting FHA loan applications may be eligible for conditional approval. Conditional approval will be valid for a period of one year from the date on which HUD notifies the applicant of the approval, unless HUD decides to allow an extension of the period of conditional approval for an additional one-year period. During the conditional approval period, HUD may impose limits on the number of loan applications that may be submitted, or the number of units or dollar amount per loan application, or any combination of these limits.

(ii) To be eligible for conversion to full MAP approval status, the lender or underwriter must, during the period of conditional approval:

(A) Underwrite and submit to HUD loan applications that result in Firm Commitments from HUD, in a minimum number as specified by HUD at the time conditional approval is granted, in accordance with the applicant's experience;

(B) Satisfy any additional conditions that HUD has imposed on the lender or underwriter at the time the conditional approval was granted; and

(C) Demonstrate acceptable capacity to process and underwrite loan applications using FHA insurance programs for covered loan transactions for the tier for which conditional approval has been granted.

(iii) The approval of a lender or underwriter that is converted from conditional to full MAP approval status is valid, unless otherwise specified by HUD, for the remainder of the 4-year period beginning on the date that HUD notified the applicant of its initial conditional approval.

(iv) If a lender or underwriter does not comply with the requirements under paragraphs (b)(3)(ii)(A) through (C) of this section, HUD may extend the term of conditional approval or terminate the conditional approval.

§ 200.1419 Expiration of previously granted MAP approvals.

(a) *Expiration.* A MAP lender or underwriter approval that was granted by HUD prior to *[effective date of final rule to be inserted at the final rule stage]* shall expire upon the later of the following:

(1) Four years following the date on which the approval was granted;

(2) Forty-five days following the lender's or underwriter's receipt of a letter from HUD inviting the lender or underwriter to apply for tier approval, if by such date the lender or underwriter has not submitted an application in accordance with § 200.1413(c) or 1415(b); or

(3) Upon HUD's notification of the lender or underwriter of the action HUD has taken on the lender or underwriter's application submitted in accordance with § 200.1413(c) or § 200.1415(b), provided that the lender or underwriter submitted the application within 45 days of the date of the lender or underwriter's receipt of a letter from HUD inviting the lender or underwriter to apply for tier approval.

(b) *One-time approval at Tier 1 in absence of submission.* A lender whose MAP approval was granted by HUD prior to *[effective date of final rule to be inserted at final rule stage]* and that does not submit an application in accordance with § 200.1413(c) within 45 days following the lender's receipt of a letter from HUD inviting the lender to apply for tier approval, shall be eligible for approval at Tier 1 for a period of time as provided in § 200.1417(b).

§ 200.1421 Renewal of lender approval.

(a) No later than 90 days before the date of the expiration of MAP-lender approval, the MAP lender may submit an application, in such form as required by HUD, for renewal of MAP-lender approval. The application for renewal must demonstrate that the lender continues to meet the applicable eligibility requirements under § 200.1411 and § 200.1413 of this part.

(b) HUD will review a lender's application for renewal of MAP approval, along with any information provided by HUD offices to which the applicant's loan applications or exhibits have been submitted within the previous approval period or periods, up to a maximum of 4 years. HUD may determine that the lender's experience or the performance of the lender's loans endorsed during the preceding 4 years is not sufficient for the lender to renew its approval at the current tier. In considering an application for renewal of MAP approval, HUD will follow the procedures and may take any action described in § 200.1417.

§ 200.1423 Adjustment of approval to a higher tier.

(a) An approved lender or underwriter may submit an application, in such form as required by HUD, for approval at a higher tier. The lender or underwriter must demonstrate that it meets the applicable eligibility requirements for the tier of approval that the lender or underwriter is seeking.

(b) HUD will review a lender or underwriter's application for MAP approval at a higher tier, along with any information provided by HUD offices where the applicant's loan applications or exhibits have been submitted within the previous approval period or periods, up to a total period of time as published by HUD for public comment. In considering an application for MAP approval at a higher tier, HUD will follow the procedures and may take any action described in § 200.1417. Approval of a MAP lender at a higher tier shall be valid as provided in § 200.1417(a)(1).

§ 200.1425 Post-approval underwriter training requirement.

Newly approved MAP underwriters must attend a MAP training session provided or approved by HUD in order to be eligible to satisfy the underwriter requirement at § 200.1411(a)(2).

§ 200.1427 Inactive underwriters.

An underwriter who at the time of the lender's annual certification to HUD pursuant to § 200.1407(d) has not submitted a pre-application or application for Firm Commitment for a period of 2 years will be designated as inactive. Inactive underwriters may be terminated from the MAP program because of inactivity and, if so, must reapply for approval to participate in MAP programs.

§ 200.1429 Appeals.

(a) An applicant may submit a written appeal of any HUD decision regarding the applicant under §§ 200.1411 through 200.1427 of this subpart. Any such appeal must be submitted to the designated HUD appeal official within 30 days of the date of receipt of HUD's written notification to the applicant of HUD's decision. HUD's written notification will advise who is the designated HUD appeal official and provide the address for such official. The written appeal may set forth the reasons why the HUD decision should be reconsidered or changed, or may request an informal conference, or both.

(b) HUD will respond to an applicant's appeal within 60 days from the date of HUD's receipt of the written appeal. If HUD's response to the appeal is to confirm HUD's original decision, no further appeal will be accepted from the applicant.

3. Immediately before § 200.1500, add an undesignated heading, to read as follows:

Map Lender Quality Assurance Enforcement

4. In § 200.1505, revise paragraph (c) to read as follows:

§ 200.1505 Warning letter.

* * * * *

(c) *Relationship to other sanctions.* The issuance of a warning letter is not subject to the procedures in § 200.1535, and is not a prerequisite to the probation, or suspension, or termination of MAP privileges.

5. In § 200.1510, revise paragraphs (a) and (b)(1) to read as follows:

§ 200.1510 Probation.

(a) *In general.* HUD may place a lender on probation, in accordance with the procedures of § 200.1535.

(b) *Effect of probation.* (1) Probation is intended to be corrective in nature and not punitive. As a result, release from probation is conditioned upon the lender meeting a specific requirement or requirements, such as replacement of a staff member. A lender's failure to take prompt corrective action after being placed on probation may be the basis for a recommendation of either suspension or termination.

* * * * *

6. In § 200.1515, revise paragraph (a) to read as follows:

§ 200.1515 Suspension of MAP privileges.

(a) *In general.* HUD may suspend a lender's eligibility for MAP, in accordance with the procedures of § 200.1535.

* * * * *

7. In § 200.1520, revise paragraph (a) to read as follows:

§ 200.1520 Termination of MAP privileges.

(a) *In general.* Except as provided in paragraph (b) of this section, HUD may terminate a lender's MAP privileges in accordance with the procedures of § 200.1535.

* * * * *

8. In § 200.1525, revise paragraph (a) to read as follows:

§ 200.1525 Settlement agreements.

(a) HUD staff, as authorized, may negotiate a settlement agreement with a MAP lender before or after the issuance of a warning letter or referral to HUD.

* * * * *

9. In § 200.1535, revise the heading and paragraphs (a)(1) and (a)(2), paragraph (b) introductory text, and (f)(1) to read as follows:

§ 200.1535 Procedures for imposition of sanctions.

(a) *Authority.* (1) *Sanctions.* HUD may impose appropriate sanctions on a MAP lender after:

(i) Conducting an impartial review of all information and documentation submitted to HUD; and

(ii) Making factual determinations that there has been a violation of MAP requirements.

(2) *Settlement agreements.* HUD is authorized to approve settlement agreements in accordance with § 200.1525 of any pending matter.

* * * * *

(b) *Notice of violation.* Before HUD reviews a matter for consideration of a sanction, HUD will issue written notice of violation to the MAP lender's contact person as listed on the Multifamily MAP Web site. The notice is sent by overnight delivery and must be signed for by an employee of the MAP lender upon receipt. The notice:

* * * * *

(f) *HUD action.* (1) HUD will consider the evidence included in the administrative record and make a final decision concerning the matter. Any record of confidential communications within HUD at this stage of the proceedings is privileged from disclosure and will not be regarded as a part of the administrative record of any matter.

* * * * *

10. Revise the heading of § 200.1545 to read as follows:

§ 200.1545 Appeals of sanction decisions.

* * * * *

Dated: March 16, 2012.

Carol J. Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–8705 Filed 4–11–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1109]

RIN 1625–AA09

Drawbridge Operation Regulation; Sturgeon Bay Ship Canal, Sturgeon Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a drawbridge operating schedule for the Maple-Oregon and Michigan Street Bridges across the Sturgeon Bay Ship Canal, at miles 4.17 and 4.3, in Sturgeon Bay, Wisconsin. The establishment of this schedule is necessary due to the construction of the Maple-Oregon Street Bridge and the completed rehabilitation of the Michigan Street Bridge. The proposed regulation also confirms the winter drawbridge schedules for all three drawbridges over Sturgeon Bay Ship Canal, including the two bridges above and the Bayview Bridge at mile 3.0.

DATES: Comments and related material must reach the Coast Guard on or before: May 14, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2011–1109 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* (202) 493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Lee Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone (216) 902–6085, email *Lee.D.Soule@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–1109), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rules'' and insert ''USCG–2011–1109'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2011–1109'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Basis and Purpose

The proposed rule establishes drawbridge schedules following the construction of the new Maple-Oregon Street Bridge and the extensive rehabilitation of the existing Michigan Street Bridge. The proposed rule is expected to provide for the safe and efficient passage of vessels requiring drawbridge openings, as well as the efficient movement of vehicular traffic in Sturgeon Bay.

The Sturgeon Bay Ship Canal is approximately 8.6 miles long and provides a navigable connection between Lake Michigan and Green Bay. The area experiences a significant increase in vehicular and vessel traffic during the peak tourist and navigation season between approximately Memorial Day and Labor Day each year. There are a total of three highway drawbridges across the waterway. The Michigan Street Bridge provides unlimited vertical clearance in the open position and 14 feet in the closed position. Maple-Oregon Bridge, provides unlimited vertical clearance in the open position and 25 feet in the closed position. Bayview Bridge provides unlimited vertical clearance in the open position and 42 feet in the closed position. Both Michigan Street and Maple-Oregon Bridges serve the downtown Sturgeon Bay area and are located approximately 750-feet apart on the canal.

A final rule was published on October 24, 2005 in the **Federal Register** (70 FR 61380) to allow for one opening per hour at the Michigan Street Bridge for recreational vessels while the Maple-Oregon Bridge was constructed and the Michigan Street Bridge was rehabilitated. The final rule also included a requirement to open at any time if 20 or more vessels gathered waiting for bridge openings. A temporary final rule was published on June 5, 2009 in the **Federal Register** (74 FR 26954), effective from June 1, 2009 to November 15, 2010 that essentially shifted the one bridge opening per hour at Michigan Street Bridge to the Maple-Oregon Bridge while the rehabilitation of Michigan Street was completed and the bridge was kept in the open-to-navigation position. With both Michigan Street and Maple-Oregon Bridges operational, the one opening per hour schedule for Michigan Street is considered restrictive for vessels and could create an unsafe condition for vessel traffic that may be between the two closely located drawbridges while waiting for bridge openings. The Coast Guard issued a notice of temporary deviation from regulations that was published on May 17, 2011 in the **Federal Register** (76 FR 28309) with request for comments to implement a test drawbridge schedule for Michigan Street and Maple-Oregon Street Bridges between May 27, 2011 and September 16, 2011. The test schedule required the Michigan Street Bridge to open for recreational vessels twice an hour, on the hour and half-hour, 24-hours a day, 7 days a week, and required the Maple-Oregon Bridge to open for recreational vessels twice an hour, on the quarter hour and three-quarter hour, during the same times. The test schedule also included a change to the requirement that the bridge open if 20 or more vessels gathered at the bridge waiting for a scheduled opening. Local opinion was that an opening if at least 10 vessels were gathered would be a safer maximum number of vessels.

The Coast Guard coordinated with all local stakeholders before, during, and after the test drawbridge schedule and did not receive any adverse comments to the test schedule.

Discussion of Proposed Rule

The Wisconsin Department of Transportation (WDOT) requested scheduled drawbridge openings for both Michigan Street and Maple-Oregon Bridges so vehicular traffic congestion would not develop on downtown Sturgeon Bay streets due to unscheduled bridge openings. This proposed rule provides at least two bridge openings per hour for both Michigan Street and Maple-Oregon Street bridges, compared to the one bridge opening per hour that was in place during the construction and rehabilitation of the two highway bridges. It also retains the test schedule requirement to open the bridge if at least 10 vessels have accumulated at either bridge waiting for an opening. The proposed rule also establishes the winter operating date for Maple-Oregon Bridge (January 1 through March 14) and rearranges the order of the three drawbridges to be presented geographically in the regulatory language. The proposed rule was developed with all known stakeholders to provide for the safe and efficient movement of both vessel and vehicular traffic, including keeping the bridge openings on a scheduled basis to reduce potential vehicular traffic congestion in Sturgeon Bay. The Coast Guard did not receive any adverse comments during the test schedule and is therefore proposing to implement the test schedule as a permanent schedule for Sturgeon Bay drawbridges.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866. The Office of Management and Budget has not reviewed it under that Order. This determination is expected to improve traffic congestion and safety in the vicinity of the drawbridge and does not exclude bridge openings for vessel traffic.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. The proposed rule continues to provide at least two drawbridge openings per hour each day for recreational vessels during peak hours compared to one opening per hour under the current regulation. Additionally, all vessels that do not require bridge openings may transit the drawbridges at any time. All known small entities were consulted and included in the development of the test drawbridge schedule in 2011, and have not provided any adverse comments.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Mr. Lee D. Soule, Bridge Management Specialist, U.S. Coast Guard, telephone 216–902–6085, email *lee.d.soule@uscg.mil*, or fax 216–902–6088. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to revise 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. Revise § 117.1101 to read as follows:

§ 117.1101 Sturgeon Bay.

(a) The Bayview (SR 42/57) Bridge, mile 3.0 at Sturgeon Bay, shall open on signal, except from December 1 through March 14, the draw shall open on signal if notice is given at least 12 hours in advance of intended passage.

(b) The draw of the Maple-Oregon Bridge, mile 4.17 at Sturgeon Bay, shall open on signal, except as follows:

(1) From March 15 through December 31, need open on signal for recreational vessels only on the quarter hour and three-quarter hour, 24 hours a day, if needed. However, if more than 10 vessels have accumulated at the bridge, or vessels are seeking shelter from severe weather, the bridge shall open on signal. This drawbridge, along with the Michigan Street drawbridge, shall open simultaneously for larger commercial vessels, as needed.

(2) From January 1 through March 14, the draw shall open on signal if notice is given at least 12 hours in advance of intended passage.

(c) The draw of the Michigan Street Bridge, mile 4.3 at Sturgeon Bay, shall open on signal, except as follows:

(1) From March 15 through December 31, need open on signal for recreational vessels only on the hour and half-hour, 24 hours a day, if needed. However if more than 10 vessels have accumulated at the bridge, or vessels are seeking shelter from severe weather, the bridge shall open on signal. This drawbridge, along with the Maple-Oregon Street drawbridge, shall open simultaneously for larger commercial vessels, as needed.

(2) From January 1 through March 14, the draw shall open on signal if notice is given at least 12 hours in advance of intended passage.

Dated: March 11, 2012.

M.N. Parks,

Rear Admiral, U. S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2012–8813 Filed 4–11–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0200]

RIN 1625–AA00

Safety Zone; International Bridge 50th Anniversary Celebration Fireworks, St Mary's River, U.S. Army Corps of Engineers Locks, Sault Sainte Marie, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a safety zone in the Captain of the Port Sault Sainte Marie zone. This proposed safety zone is intended to restrict vessels from certain portions of water areas within Sector Sault Sainte Marie Captain of the Port zone, as defined by 33 CFR 3.45–45. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays.

DATES: Comments and related materials must be received by the Coast Guard on or before May 14, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0200 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov*.

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the

''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email MST3 Kevin Moe, Prevention Department, Coast Guard, Sector Sault Sainte Marie, MI, telephone (906) 253–2429, email *Kevin.D.Moe@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0200), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2012–0200'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0200'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting, but you may submit a request for one by using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

On the evening of 28 June 2012, The International Bridge Administration will be celebrating the International Bridge 50th Anniversary. As part of that celebration, fireworks will be launched from the northeast pier of the U.S. Army Corp of Engineers Soo Locks. The Captain of the Port Sault Sainte Marie has determined that the fireworks event poses various hazards to the public, including explosive dangers associated with fireworks, and debris falling into the water.

Discussion of Proposed Rule

To safeguard against the dangers posed by the International Bridge 50th Anniversary Celebration fireworks, the Captain of the Port Sault Sainte Marie has determined that a temporary safety zone is necessary. Thus, the Captain of the Port Sault Sainte Marie proposes to establish a safety zone on the St. Mary's River to include all waters within a 750-foot radius around the eastern portion of the U.S. Army Corp of Engineers Soo Locks North East Pier, centered in position: 46°30′19.66″ N, 084°20′31.61″ W.

This proposed safety zone will be effective and enforced from 10 p.m. until 12 p.m. on June 28, 2012. Entry into, transiting, or anchoring within the proposed safety zone is prohibited unless authorized by the Captain of the Port Sector Sault Sainte Marie, or his on-scene representative. All persons and vessels authorized to enter the proposed safety zone shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene representative. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard determined that this rulemaking would not be a significant regulatory action because the safety zone will be relatively small and enforced for a relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters in that vessels may still transit unrestricted portions of the waterways. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port Sault Sainte Marie.

On the whole, the Coast Guard expects insignificant adverse impact to mariners from the enforcement of this proposed safety zone.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit around the eastern portion of the U.S. Army Corp of Engineers Soo Locks North East Pier, Sault Sainte Marie Michigan, between 10 p.m. and 12 p.m. on June 28, 2012.

This proposed safety zone will not have a significant economic impact on a substantial number of small entities for the following reason; this rule will be in effect for only two hours. Vessel traffic may still safely pass outside the safety zone during the event. In the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Sault Sainte Marie to transit through the safety zone. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If this proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact MST3 Kevin Moe, Prevention Department, Coast Guard Sector Sault Sainte Marie, MI at (906) 253–2429. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

Taking of Private Property

This proposed rule will not affect the taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this preliminary determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves the establishment of a safety zone and therefore paragraph (34)(g) of figure 2–1 applies. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T09–0200 to read as follows:

§ 165.T09–0200 Safety Zone International Bridge 50th Anniversary Celebration Fireworks, St. Mary's River, U.S. Army Corps of Engineers Locks, Sault Sainte Marie, MI.

(a) *Location.* The following area is a temporary safety zone: All U.S. navigable waters of the St. Mary's River within a 750-foot radius around the eastern portion of the U.S. Army Corp of Engineers Soo Locks North East Pier, centered in position: 46°30′19.66″ N, 084°20′31.61″ W [DATUM: NAD 83].

(b) *Effective and Enforcement period.* This regulation is effective and will be enforced from 10 p.m. until 12 p.m. on June 28, 2012.

(1) The Captain of the Port, Sector Sault Sainte Marie may suspend at any time the enforcement of the safety zone established under this section.

(2) The Captain of the Port, Sector Sault Sainte Marie, will notify the public of the enforcement and suspension of enforcement of the safety zone established by this section via any means that will provide as much notice as possible to the public. These means might include some or all of those listed in 33 CFR 165.7(a). The primary method of notification, however, will be through Broadcast Notice to Mariners and local Notice to Mariners.

(c) *Definitions.* The following definitions apply to this section:

(1) Designated representative means any Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port Sault Sainte Marie to monitor these safety zones, permit entry into these safety zones, give legally enforceable orders to persons or vessels within these safety zones, or take other actions authorized by the Captain of the Port.

(2) Public vessel means a vessel owned, chartered, or operated by the United States or by a State or political subdivision thereof.

(d) *Regulations.* (1) The general regulations in 33 CFR 165.23 apply.

(2) All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port Sault Sainte Marie or a designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel shall proceed as directed.

(3) When the safety zone established by this section is being enforced, all vessels must obtain permission from the Captain of the Port Sault Sainte Marie or his or her designated representative to enter, move within, or exit that safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port or his or her designated representative. While within the safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

(e) *Exemption.* Public vessels, as defined in paragraph (c) of this section, are exempt from the requirements in this section.

Dated: March 28, 2012.

J.C. McGuiness,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2012–8808 Filed 4–11–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2011–0130, FRL–9658–5]

Approval and Promulgation of Air Quality Implementation Plans; State of Nevada; Regional Haze State and Federal Implementation Plans; BART Determination for Reid Gardner Generating Station

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove the remaining portion of a revision to the Nevada State Implementation Plan (SIP) to implement the regional haze program for the first planning period through July 31, 2018. This Notice proposes to approve the chapter of Nevada's Regional Haze SIP that requires Best Available Retrofit Technology (BART) for emissions limits of oxides of nitrogen (NO_X) from Units 1 and 2 at the Reid Gardner Generating Station (RGGS). We are proposing to disapprove the NO_X emissions limit for Unit 3. We are also proposing to disapprove the provision of the RGGS BART determination that sets a 12-month rolling average for Units 1 through 3. This Notice proposes to promulgate a Federal Implementation Plan (FIP) that establishes certain requirements for which the State, in a letter dated March 22, 2012, has agreed to submit a SIP revision. The FIP sets an emissions limit of 0.20 lbs/MMBtu (pounds per million British thermal units) for Unit 3 as BART and requires the determination of emissions from Units 1 through 3 based on a 30-day rolling average (averaged across all three units). In a prior action, EPA approved Nevada's Regional Haze SIP except for its BART determination for NO_X for RGGS Units 1 through 3.

DATES: Comments: Written comments must be received at the address below on or before May 14, 2012.

Public Hearing: We will hold a public hearing in early May at a location near the Facility. We will post information on the specifics on our Web site at *http://www.epa.gov/region9/air/actions/nv.html#haze* and by publishing a notice in a general circulation newspaper at least 15 days before the date of the hearing.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2011–0130 by one of the following methods:

1. *Federal Rulemaking portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. *Email: Webb.Thomas@epa.gov.*

3. *Fax:* 415–947–3579 (Attention: Thomas Webb)

4. *Mail:* Thomas Webb, EPA Region 9, Planning Office, Air Division, 75 Hawthorne Street, San Francisco, California 94105.

5. *Hand Delivery or Courier:* Such deliveries are only accepted Monday through Friday, 8:30 a.m.–4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R09–OAR–2011–0130. Our policy is that EPA will include all comments received in the public docket without change. EPA may make comments available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *http://www.regulations.gov,* EPA will include your email address as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although it is listed in the index, some information is not publicly available (e.g., CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, voluminous records or large maps, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Planning Office of the Air Division, Air-2, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. EPA requests you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy material of the docket. You may view the hard copy material of the docket Monday through Friday, 9–5:30 PST, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Thomas Webb, U.S. EPA, Region 9, Planning Office, Air Division, Air-2, 75 Hawthorne Street, San Francisco, CA 94105. Thomas Webb can be reached at telephone number (415) 947–4139 and via electronic mail at *webb.thomas@epa.gov.*

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(1) The initials BART mean or refer to Best Available Retrofit Technology
(2) The initials CAA mean or refer to Clean Air Act
(3) The initials CCM mean or refer to EPA's Control Cost Manual
(4) The words or initials EPA, we, us or our mean or refer to the United States Environmental Protection Agency
(5) The initials GCNP mean or refer to Grand Canyon National Park
(6) The initials IMPROVE mean or refer to Interagency Monitoring of Protected Visual Environments
(7) The word Jarbidge means or refers to the Jarbidge Wilderness Area
(8) The initials LNB mean or refer to low NO_X burners
(9) The initials LTS mean or refer to Long-Term Strategy
(10) The initials NDEP mean or refer to Nevada Division of Environmental Protection
(11) The words Nevada and State mean or refer to the State of Nevada
(12) The initials NO_X mean or refer to nitrogen oxides
(13) The initials OFA mean or refer to overfire air
(14) The initials RGGS means or refers to Reid Gardner Generating Station Units 1 through 3
(15) The initials RHR mean or refer to Regional Haze Rule
(16) The initials ROFA mean or refer to rotating overfire air
(17) The word Rotamix means or refers to a technology that combines a conventional SNCR system with a proprietary air and reagent injection system
(18) The initials RPG mean or refer to Reasonable Progress Goal
(19) The initials SCR mean or refer to selective catalytic reduction
(20) The initials SIP mean or refer to State Implementation Plan
(21) The initials FIP mean or refer to Federal Implementation Plan
(22) The initials SNCR mean or refer to selective non-catalytic reduction
(23) The initials TSD mean or refer to Technical Support Document

Table of Contents

I. Background

The CAA requires each state to develop plans, referred to as SIPs, to meet various air quality requirements. A state must submit its SIPs and SIP revisions to us for approval. Once approved, a SIP is enforceable by EPA and citizens under the CAA, and is, therefore, federally enforceable. If a state fails to make a required SIP submittal or if we find that a state's required submittal is incomplete or unapprovable, then we must promulgate a FIP to fill this regulatory gap. CAA section 110(c)(1). 40 U.S.C. 7410(c).

This proposed action is intended to fulfill the requirement that states adopt and EPA approve SIPs that address regional haze. In 1990, Congress added section 169B to the CAA to address regional haze issues, and we promulgated regulations addressing regional haze in 1999. 64 FR 35714 (July 1, 1999), codified at 40 CFR part 51, subpart P. For a more detailed discussion please see our prior proposed action at 76 FR 36450 (June 22, 2011).

II. State Submittals and EPA's Prior Action

The Nevada Division of Environmental Protection (NDEP) adopted and transmitted its ''Nevada Regional Haze State Implementation Plan'' (Nevada RH SIP) to EPA Region 9 with a letter dated November 18, 2009. The Nevada RH SIP was complete by operation of law on May 18, 2010. Nevada provided public notice and held a public hearing on the proposed Best Available Retrofit Technology (BART) controls for four stationary sources, including RGGS, on April 23, 2009. The State submitted to EPA additional documentation of public process and adoption of a more stringent emission limit for one of the BART sources on February 18, 2010. Revised Nevada Division of Environmental Protection BART Determination Review of NV Energy's Reid Gardner Generation Station Units 1, 2 and 3, Revised October 22, 2009 (hereinafter ''RGGS BART Determination''). Nevada included in its SIP submittal NDEP's responses to written comments from EPA Region 9, the National Park Service, and a consortium of conservation organizations. NDEP responded to comments on its RGGS BART Determination for NO_X in two sections of its documents.[1]

On June 22, 2011, EPA proposed to approve the entire Nevada Regional Haze SIP submittal, including the RGGS BART Determination. 76 FR 36450 (June 22, 2011). EPA received adverse comments on the proposed approval, including specific comments on NDEP's modeling and cost analysis of the RGGS BART Determination for NO_X. See Modeling for the Reid Gardner Generating Station: Visibility Impacts in Class I Areas, Prepared by H. Andrew Gray, Ph.D., August 2011 and Review of EPA's Proposed Approval of a Revision to the State of Nevada's State Implementation Plan to Implement the Regional Haze Program, Comments on Determination of Best Available Retrofit Technology, August 22, 2011, prepared by Petra Pless, D. Env. and Bill Powers, P.E. [2] (''Pless Powers Report'').

On December 13, 2011, EPA signed its final approval of the Nevada RH SIP submittal that was published in the **Federal Register** on March 26, 2012. 77 FR 17334 (March 26, 2012). In our final approval, we delayed taking any action on the Nevada's RGGS BART Determination for NO_X.[3] EPA indicated that we needed additional time to consider the substantial comments submitted on the RGGS BART Determination for NO_X.

On December 22, 2011, we sent a letter via email to NDEP requesting clarification on several issues related to the comments on the RGGS BART Determination for NO_X.[4] NDEP responded on February 6 and February 14, 2012 by providing us with cost-related information. These cost estimates consisted of updates to specific line items in order to reflect September 2011 material costs, but did not include any supporting information such as detailed equipment lists, vendor quotes, or the design basis for line item costs.

EPA requested further information from NDEP on March 14, 2012 regarding the emissions limit that NDEP had proposed as BART for Unit 3.[5] Comments submitted on our June 22, 2011, proposed approval indicated that the actual average emission rate that RGGS reported for Unit 3 was significantly lower than NDEP's BART emissions limit for NO_X of 0.28 lb/MMBtu. Pless Powers at 48. EPA also requested information regarding NDEP's basis for allowing a 12-month rolling average for NO_X for Units 1–3, which was also raised as an issue in the comments. Pless Powers at 52.

In response, NDEP informed EPA on March 22, 2012 that it had conducted further analysis resulting in NDEP's conclusion to lower the BART emissions limit for Unit 3 BART for NO_X to 0.20 lb/MMBtu.[6] NDEP also informed EPA that its further analysis supported determining the NO_X BART limit for all RGGS Units based on a 30-day rolling average rather than the 12-month rolling average contained in the adopted rules and submitted SIP, provided that compliance is determined based on a three-unit average. Finally, NDEP indicated that it had evaluated requiring Selective Non-Catalytic Reduction (SNCR) with LNB and OFA rather than ROFA with Rotamix as BART. NDEP stated that Nevada Energy had installed ROFA on Unit 4 but that it has not operated as expected. NDEP anticipated SNCR with LNB and OFA would produce more reliable performance.

The Nevada RH SIP included an evaluation of SNCR finding that it would result in a higher emissions limit for each unit than ROFA with Rotamix.[7] NDEP's recent re-evaluation has concluded that SNCR with LNB and OFA would result in a NOx BART emissions limit of 0.20 lb/MMBtu for Units 1 through 3. NDEP indicates that it will submit a SIP revision by September 2012 that evaluates the substitution of SNCR with LNB and OFA for ROFA with Rotamix, lowers the NO_X BART limit for RGGS Unit 3, and requires a NO_X emissions limit of 0.20 lb/MMBtu on a 30-day rolling average (averaged across all three units).[8]

III. Overview of Proposed Action

Today's proposal addresses the RGGS BART Determination for NO_X, and if finalized, will complete our action on the Nevada Regional Haze SIP submitted on November 18, 2009. In its BART determination of RGGS, NDEP considered several control technologies, including Selective Catalytic Reduction (SCR), SNCR and ROFA with Rotamix. NDEP concluded that SCR would result in a very small incremental improvement of visibility over other technologies, which did not justify the incremental cost of installing and operating SCR. The results of our own analysis of the incremental visibility improvement and cost for SCR differ from NDEP's analysis in certain respects, but support NDEP's decision to establish a NO_X BART emission limit that could be achieved with ROFA and Rotamix (or SNCR) rather than requiring an emission limit consistent with SCR technology. This proposal and our TSD provide additional information concerning our approval of NDEP's determination that SCR is not required as BART for RGGS. We considered the comments that we received on our June 22, 2011, proposed approval. We also conducted an independent modeling analysis to evaluate the incremental visibility improvement attributable to the NO_X emission rates indicated in the RH SIP. Our analysis examined the visibility improvement that would be expected by requiring RGGS to meet a NO_X emission limit of 0.06 lbs/MMbtu based on installation and operation of SCR. Our proposed approval is based in large part on this modeling analysis, discussed in detail below and in the TSD, showing that SCR controls at RGGS would not result in enough incremental visibility improvement at a

[1] See Appendix C (starting at C–8) and D (starting at D–141) of the NV Regional Haze SIP, available as attachments to EPA–R09–OAR–2011–0130–0003.

[2] Both reports can be found as attachments to EPA–R09–OAR–2011–0130–0062, with supporting information located in –0063.

[3] 77 FR 17334.

[4] Email dated December 22, 2011, from Colleen McKaughan (EPA) to Mike Elges (NDEP) and others.

[5] Email dated March 14, 2012, from Colleen McKaughan (EPA) to Mike Elges (NDEP).

[6] Letter dated March 22, 2012 from Mike Elges (NDEP) to Deborah Jordan (EPA).

[7] As indicated by controlled emission rates summarized in Table 1, NDEP Reid Gardner BART Determination, October 22, 2009. Available as Docket Item No. EPA–R09–OAR–2011–0130–0005.

[8] Letter dated March 22, 2012, from Mike Elges (NDEP) to Deborah Jordan (EPA).

single Class I area to justify the incremental cost of the technology.[9]

Therefore, we are proposing to approve NDEP's determination that NO_X BART for Units 1 and 2 is a limit of 0.20 lbs/MMBtu, which can be achieved with ROFA with Rotamix, or with SNCR with LNB and OFA. We are proposing to disapprove NDEP's NO_X BART determination for RGGS Unit 3 and the SIP's provision to measure NO_X emissions from Units 1 through 3 on a 12-month rolling average. Because we are proposing to disapprove these provisions of the SIP, we are concurrently proposing a FIP. Our FIP proposes promulgating a NO_X BART emissions limit for RGGS Unit 3 of 0.20 lbs/MMbtu. We are also proposing a FIP provision requiring that NO_X emissions for RGGS Units 1 through 3 are measured on a rolling 30-day average (across all three units). Our justification for our proposed disapproval and proposed FIP provisions is discussed in detail in our Technical Support Document (TSD) in the docket for this Notice.

IV. Requirements for Regional Haze SIPs

A. Regional Haze Rule

Regional haze SIPs must establish a long-term strategy that ensures reasonable progress toward achieving natural visibility conditions in each Class I area affected by the state's emissions. For a further discussion of this topic, please see our Notice of Proposed Rulemaking. 76 FR 36450 (June 22, 2011).

B. Best Available Retrofit Technology

Section 169A of the CAA directs states to evaluate the use of retrofit controls at certain larger, often uncontrolled, older stationary sources in order to address visibility impacts from these sources. Specifically, section 169A(b)(2)(A) of the CAA requires states to revise their SIPs to contain such measures as may be necessary to make reasonable progress towards the natural visibility goal, including a requirement that certain categories of existing major stationary sources[10] built between 1962 and 1977 procure, install, and operate the ''Best Available Retrofit Technology'' as determined by the state. Under the RHR, states are directed to conduct BART determinations for such ''BART-eligible'' sources that may be anticipated to cause or contribute to any visibility impairment in a Class I area.

C. Roles of Agencies in Addressing Regional Haze

Successful implementation of the regional haze program will require long-term coordination among states, tribal governments and various federal agencies. EPA published on July 6, 2005, the *Guidelines for BART Determinations under the Regional Haze Rule* at Appendix Y to 40 CFR part 51 (hereinafter referred to as the ''BART Guidelines'') to assist states in determining which of their sources should be subject to the BART requirements and in determining appropriate emission limits for each applicable source. In making a BART determination for a fossil fuel-fired electric generating plant with a total generating capacity in excess of 750 megawatts, a state must use the approach set forth in the BART Guidelines. In contrast, however, our BART Guidelines encourage, but do not require, States to follow the BART Guidelines in making BART determinations for other types of sources, including fossil fuel-fired electric generating plants with a total generating capacity that is less than 750 megawatts. 70 FR 39104, 39108 (July 6, 2005) (''The better reading of the Act indicates that Congress intended the guidelines to be mandatory only with respect to 750 megawatt power plants.'') The CAA, therefore, allows States to exercise broader discretion in applying the BART guidelines to power plants that are smaller than 750 megawatts, such as RGGS. Id.

In their SIPs, states must document their BART control determination analyses. In making BART determinations, section 169A(g)(2) of the CAA requires that states consider the following factors: (1) The costs of compliance; (2) the energy and non-air quality environmental impacts of compliance; (3) any existing pollution control technology in use at the source; (4) the remaining useful life of the source; and, (5) the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology. States are free to determine the weight and significance assigned to each factor, and as discussed above, generally have greater latitude in this determination for power plants that are smaller than 750 megawatts.

A regional haze SIP must include source-specific BART emission limits and compliance schedules for each source subject to BART. Once a state has made its BART determination, the BART controls must be installed and in operation as expeditiously as practicable, but no later than five years after the date EPA approves the regional haze SIP. CAA section 169(g)(4). 40 CFR 51.308(e)(1)(iv). In addition to what is required by the RHR, general SIP requirements mandate that the SIP must also include all regulatory requirements related to monitoring, recordkeeping and reporting for the BART controls on the source.

D. Lawsuits

In two separate lawsuits, environmental groups sued EPA for our failure to take timely action with respect to the regional haze requirements of the CAA and our regulations. In particular, the lawsuits alleged that we had failed to promulgate FIPs for these requirements within the two-year period allowed by CAA section 110(c) or, in the alternative, fully approve SIPs addressing these requirements. EPA entered into a Consent Decree agreeing to sign a **Federal Register** Notice taking action on the Nevada RH SIP by December 13, 2011. The litigants agreed to extend our time for taking action on the RGGS NO_X BART determination portion of the Nevada SIP given the extensive comments we received on our June 22, 2011, proposed approval. Our proposed action today meets our agreement with the litigants.

V. EPA's Analysis of Nevada's RH SIP

A. Affected Class I Areas

There are four Class I areas within a 300 kilometer (km) radius of RGGS: Grand Canyon National Park, Bryce Canyon National Park, Zion National Park and Sycamore Canyon Wilderness. Joshua Tree National Monument is just on the border of the 300 km radius of RGGS. Of these, GCNP is the nearest area to RGGS, located at a distance of 85 km.

B. Identification of Sources Subject to BART

EPA's final approval of the Nevada RH SIP agreed with NDEP's determination of its BART-eligible sources within the state, and its determination of which sources were subject to BART based on their contribution to visibility impairment. EPA's final approval included NDEP's BART determinations for the Tracy, Fort Churchill, and Mohave electrical generating stations.[11] In our final approval of the Nevada RH SIP, we took no action on NDEP's NO_X BART Determination for RGGS.

[9] In NDEP/Nevada Energy's analysis, and in our analysis, the highest impacted Class I area is Grand Canyon National Park.

[10] The set of ''major stationary sources'' potentially subject to BART is listed in CAA section 169A(g)(7).

[11] 77 FR 17334.

C. Evaluation of Nevada's NO_X BART Determination for Reid Gardner Generating Station

Background: Reid Gardner is a coal-fueled, steam-electric generating plant with four operating units producing a total of 557 MW. Three of the units, built in 1965, 1968, and 1976 are BART-eligible, and were determined by NDEP to be subject to BART. Each of these units produces about 100 MW with steam boilers that drive turbine-generators. At present, the units are equipped with LNB and over-fire air (OFA) systems, mechanical collectors for particulate control, wet scrubbers that use soda ash for sulfur dioxide (SO_2) removal, as well as recently installed baghouses. NDEP's review of Nevada Energy's BART report for RGGS resulted in NDEP agreeing only with the control technologies proposed as BART for SO_2 and PM_{10}.[12]

NO_X BART Determination: NDEP performed a five-factor analysis for the BART-eligible units at RGGS that included several feasible technologies including SCR, SNCR, and ROFA with Rotamix, among other control technologies. NDEP eliminated SCR-based options and determined that BART controls for NO_X are rotating opposed fire air (ROFA) with Rotamix for Units 1 through 3. For this control technology, NDEP determined emission limits, based on a rolling 12-month average, of 0.20 lb/MMBtu for Units 1 and 2, and 0.28 lb/MMBtu for Unit 3. In its five factor analysis, NDEP eliminated SCR because it gave significant weight to the incremental cost of compliance. NDEP also cited the relatively low visibility improvement at GCNP that would result from SCR over ROFA with Rotamix.

EPA has carefully reviewed NDEP's BART analysis, focusing primarily on the incremental cost of compliance and incremental degree of improvement of visibility between SCR and ROFA with Rotamix. After receiving extensive comments in August 2011, we performed a significant amount of additional analysis for these two factors, including revisions to control cost calculations and new CALPUFF visibility modeling.

1. Costs of Compliance

NDEP's analysis: NDEP evaluated the costs of compliance for each feasible NO_X control option by analyzing the average and incremental cost effectiveness of each control technology. Average cost effectiveness ($/ton) is based on the total annualized cost ($) of a control option divided by the total amount of NO_X removed (tons) by that control option. Incremental cost effectiveness is calculated when considering one control technology in relation to another, and examines the differing costs and the differing NO_X removal ability of the two control options.

When moving from a less stringent to a more stringent NO_X control technology, the more stringent technology will result in greater amounts of NO_X removal, but will also typically be more expensive. Incremental cost ($/ton) is calculated by dividing the difference in annualized costs ($) of the two technologies by the difference in NO_X removal (ton) of the two technologies. Incremental costs are typically calculated ''in order'', by comparing one control technology with the less stringent technology immediately preceding it. The control cost data that NDEP included in the RH SIP and relied upon in making its NO_X BART determination is summarized in Table 1 below.

TABLE 1—SUMMARY OF NDEP NO_X BART DETERMINATION RESULTS FOR RGGS UNIT 1 THROUGH 3 (AS INCLUDED IN THE RH SIP)

Control option	Control efficiency [1] (%)	Emission rate [1] (lb/MMBtu)	Emission reduction [1] (ton/yr)	Annualized costs [1] ($MM)	Average cost effectiveness [1] ($/ton)	Incremental cost effectiveness [1] ($/ton)
Reid Gardner Unit 1						
LNB + OFA (enhanced)	21.3	0.36	483	$0.55	$1,143	$1,143
LNB + OFA + SNCR	40.9	0.27	927	1.13	1,222	1,308
ROFA + Rotamix	57.7	0.2	1308	1.45	1,109	833
SCR + LNB + OFA	81.6	0.085	1850	4.75	2,566	6,085
SCR + ROFA [3]	81.6	0.085	1850	5.39	2,916	7,280
Reid Gardner Unit 2						
LNB + OFA (enhanced)	23.7	0.355	580	0.55	952	952
LNB + OFA + SNCR	42.7	0.267	1044	1.16	1,106	1,299
ROFA + Rotamix	59.0	0.19	1443	1.50	1,038	860
SCR + LNB + OFA	82.2	0.083	2010	4.80	2,386	5,813
SCR + ROFA [3]	82.2	0.083	2010	5.47	2,721	7,001
Reid Gardner Unit 3						
LNB + OFA (enhanced)	6.5	0.42	147	0.55	3,742	3,742
LNB + OFA + SNCR	29.9	0.316	678	1.08	1,596	1,000
ROFA + Rotamix	38.0	0.278	869	1.38	1,588	1,560
SCR + LNB + OFA	78.2	0.098	1774	4.72	2,660	3,688
SCR + ROFA [2]	78.2	0.098	1774	5.40	3,045	4,444

[1] As summarized in Table 1, NDEP Reid Gardner BART Determination, October 22, 2009. Available as Docket Item No. EPA–R09–OAR–2011–0130–0005.
[2] Incremental cost effectiveness based on ROFA + Rotamix as previous control technology.

[12] EPA approved that portion of NDEP's BART determination for RGGS on December 13, 2011.

The annualized costs listed in Table 1 are based on total capital installation costs and certain annual operating costs submitted to NDEP by Nevada Energy in its BART analysis. These costs were relied upon by NDEP and included in the SIP without modification. These cost calculations provided line item summaries of capital costs and annual operating costs, but did not provide further supporting information such as detailed equipment lists, vendor quotes, or the design basis for line item costs.

In its RH SIP, NDEP indicated that it based its NO_X BART determination of ROFA with Rotamix rather than SCR primarily on the incremental costs of compliance. NDEP judged the costs of ROFA with Rotamix as cost effective based on an average cost effectiveness of approximately $1100–1600/ton, as seen in Table 1. NDEP then eliminated more stringent control options, such as the SCR-based options, based on high incremental cost effectiveness. Specifically, NDEP stated that ''the $/ton of NO_X removed increased significantly * * * without correspondingly significant improvements in visibility.'' [13] Per NDEP estimates, the incremental cost effectiveness of SCR with LNB and OFA is approximately $3,600–6,100/ton. NDEP determined that this additional incremental cost per ton for SCR technologies did not appear cost effective compared to the incremental visibility improvement achieved by the SCR-based control options.

EPA's analysis: In reviewing the Nevada RH SIP and public comments, we identified several aspects of NDEP's approach to this factor with which we disagreed, and for which we have performed additional analysis. We received several public comments that NDEP's cost calculations were overestimated and based on methodology inconsistent with EPA's Control Cost Manual (CCM).[14] We agree that NDEP included inappropriate costs and our analysis excludes those costs that are not allowed by the CCM. Therefore, we have revised these cost calculations and adjusted the value of specific variables to conform to values allowed by the CCM. Aside from these items, other commenters alleged that aspects of NDEP's cost estimates were unjustified or overestimated, such as a failure to account for multiple unit discount and overestimated reagent costs.[15] We agree that the record does not support the positions that NDEP has taken on these cost items. However, we did not account for these additional discrepancies in our revised cost estimate since disallowing those costs not in the CCM resulted in our finding that SCR is cost effective. The disallowed costs result in a decrease of 25–33 percent in the average and incremental cost effectiveness of the control technology options. Detailed cost calculations, in which we revised the original cost calculations (as included in the RH SIP) and the updated cost calculations (as provided by NDEP on February 14, 2012) for each NO_X control technology, are included in Appendix A of our TSD. Summarized in Table 2 below is a comparison of the updated NDEP cost calculations (as provided on February 14, 2012) and our revised cost calculations for the SCR with LNB and OFA control technology option.

TABLE 2—COST EFFECTIVENESS COMPARISON—SCR WITH LNB AND OFA

Unit No.	Average cost effectiveness ($/ton)		Incremental cost effectiveness ($/ton)	
	NDEP	EPA revised	NDEP	EPA revised
Unit 1	$2,827	$2,110	$6,370	$4,534
Unit 2	2,627	1,967	6,080	4,330
Unit 3	2,932	2,183	3,856	2,756

Based on our revised cost estimates, we do not consider these average and incremental cost effectiveness values for SCR with LNB and OFA as cost prohibitive. Our analysis of this factor indicates that costs of compliance (average and incremental) are not sufficiently large to warrant eliminating SCR from consideration.

The incremental cost effectiveness values for Units 1 and 2 are around $4,500/ton. Although EPA does not consider this incremental cost prohibitive, we note that the State has certain discretion in weighing this cost. Because RGGS is not a facility over 750 megawatts and therefore not subject to EPA's presumptive BART limits, the State may exercise its discretion more broadly in this particular determination.

2. Degree of Visibility Improvement

NDEP's Analysis: As part of its BART analysis, Nevada Energy performed visibility modeling in order to evaluate the visibility improvement attributable to each of the NO_X control technologies that it considered. Results of the visibility modeling performed by Nevada Energy in its submittal to NDEP are summarized in Table 3 below.

[13] Revised NDEP Reid Gardner BART Determination Review, page 6. Available as Docket Item No. EPA–R09–OAR–2011–0130–0005.

[14] See comments from NPCA Consortium (EPA–R09–OAR–2011–0130–0062), National Park Service and U.S. Fish and Wildlife Service (EPA–R09–OAR–2011–0130–0054) and in expert report by Petra Pless/Bill Powers (attachment to EPA–R09–OAR–2011–0130–0062).

[15] These items were primarily noted in the expert report by Petra Pless/Bill Powers (attachment to EPA–R09–OAR–2011–0130–0062).

TABLE 3—SUMMARY OF NEVADA ENERGY ESTIMATES OF VISIBILITY BENEFIT [16]

Control option	Visibility improvement (from WRAP baseline) [17]				Visibility improvement (incremental, from control)
	RGGS1 (dv)	RGGS2 (dv)	RGGS3 (dv)	Total (dv)	Total (dv)
LNB + OFA (enhanced)	0.440	0.479	0.407	1.33	
LNB + OFA + SNCR	0.521	0.560	0.485	1.57	0.24
ROFA + Rotamix	0.592	0.630	0.514	1.74	0.17
SCR + LNB + OFA	0.698	0.735	0.652	2.09	0.35
SCR + ROFA [18]	0.698	0.735	0.652	2.09	0.35

Based upon these results, the installation of SCR with LNB and OFA would result in an incremental visibility improvement at Grand Canyon National Park of 0.35 deciviews (dv). This visibility improvement is based upon the NO_X emission rates estimated by Nevada Energy in their BART analysis for each control technology option, and is relative to visibility impacts based on emissions used by the Western Regional Air Partnership (WRAP). In preparing the RH SIP, however, NDEP developed its own set of NO_X emission estimates for the various control technology options. The differences between Nevada Energy's estimates and the emission estimates that form the basis of the Nevada RH SIP are summarized in Table 4 below.

TABLE 4—COMPARISON OF NEVADA ENERGY AND NDEP CONTROL TECHNOLOGY EMISSION ESTIMATES

Control option	Nevada energy		NDEP	
	Emission factor [1] (lb/MMBtu)	Control efficiency [2] (%)	Emission factor [3] (lb/MMBtu)	Control efficiency [3] (%)
Reid Gardner Unit 1				
Baseline (LNB + OFA)	0.38		0.462	
LNB + OFA (enhanced)	0.30	21.3	0.360	21.3
LNB + OFA + SNCR	0.23	40.9	0.270	40.9
ROFA + Rotamix	0.16	57.7	0.200	57.7
SCR + LNB + OFA	0.07	81.6	0.085	81.6
SCR + ROFA	0.07	81.6	0.085	81.6
Reid Gardner Unit 2				
Baseline (LNB + OFA)	0.393		0.466	
LNB + OFA (enhanced)	0.30	23.7	0.355	23.7
LNB + OFA + SNCR	0.23	42.7	0.267	42.7
ROFA + Rotamix	0.16	59.0	0.190	59.0
SCR + LNB + OFA	0.07	82.2	0.083	82.2
SCR + ROFA	0.07	82.2	0.083	82.2
Reid Gardner Unit 3				
Baseline (LNB + OFA)	0.32		0.451	
LNB + OFA (enhanced)	0.30	6.5	0.420	6.5
LNB + OFA + SNCR	0.23	29.9	0.316	29.9
ROFA + Rotamix	0.20	38.0	0.278	38.0
SCR + LNB + OFA	0.07	78.2	0.098	78.2
SCR + ROFA	0.07	78.2	0.098	78.2

[1] From each respective unit's NVE BART Analysis, Table 3–1. Available in Docket Item No. EPA–R09–OAR–2011–0130–0007.
[2] From each respective unit's NVE BART Analysis, Table 3–2. Available in Docket Item No. EPA–R09–OAR–2011–0130–0007.
[3] As summarized in Table 1, NDEP Reid Gardner BART Determination, October 22, 2009. Available as Docket Item No. EPA–R09–OAR–2011–0130–0005. Baseline emission factor is not explicitly calculated by NDEP. The factor listed in this table represents the listed annual emissions divided by "Base Heat Input".

[16] Visibility improvement listed here are for the Class I area with the highest impact, Grand Canyon National Park. They represent the change in the 98th percentile impacts from three modeled years. The "total" is the simple total of the impacts from the three individual units, which Nevada Energy modeled separately.

[17] From Table 5–4 of NVE BART Analysis Reports, Reid_Gardner_1_10–03–08.pdf, Reid_Gardner_2_10–03–08.pdf, Reid_Gardner_3_10–03–08.pdf. Available in Docket Item No. EPA–R09–OAR–2011–0130–0007. The improvements here are relative to the "WRAP baseline", impacts from emission levels used by the Western Regional Air Partnership and modeled by Nevada Energy. This is a different "baseline" than used for the cost estimates below.

[18] Incremental visibility benefit of SCR + ROFA is based upon ROFA + Rotamix as previous control technology.

As seen in these tables, NDEP's estimates of controlled emission rates differ from Nevada Energy's estimates. These differences are a result of NDEP's use of a different emission baseline in its calculations than Nevada Energy, which is discussed below in our discussion of existing pollution control technology. Since NDEP elected to calculate controlled emission rates by retaining the respective percent reduction values for each control technology, rather than each control technology's emission rate (lb/MMBtu), the use of a higher baseline emission rate results in higher emission estimates for each control technology option. As a result, NDEP's estimated performance for each control technology is less stringent than Nevada Energy's estimates. NDEP, however, did not perform additional modeling to determine the visibility improvement attributable to its emission estimates, and continued to rely on the visibility modeling performed by Nevada Energy.

As noted in the discussion of cost of compliance, part of NDEP's basis for rejecting control technology options more stringent that ROFA with Rotamix as BART was that the incremental costs of more stringent control options were not justified relative to their corresponding increases in visibility improvement. However, without updated visibility modeling that indicates the visibility improvement attributable to NDEP's emission estimates, we do not consider NDEP to have properly considered the appropriate magnitude of incremental visibility improvement in reaching its determination. As discussed below, we have performed our own visibility modeling to determine these visibility impacts.

EPA's Analysis: In performing our own visibility modeling, the primary goal of our approach was to determine the visibility improvement associated with the NO_X emission estimates relied upon in the RH SIP. In developing a modeling strategy, we decided that an approach that consisted of simply using Nevada Energy's modeling with model emission rates updated to reflect NDEP's estimates was not appropriate. As a result of changes to CALPUFF regulatory guidance that have occurred in the intervening time since Nevada Energy performed its visibility modeling, we elected to perform our visibility modeling in a manner that more closely adheres with current EPA regulatory guidance on CALPUFF modeling. Key elements of our modeling approach that differ from Nevada Energy's modeling include:

—CALPUFF system version: We performed our visibility modeling using version 5.8 of the CALPUFF model, and version 5.8 of the CALMET meteorological preprocessor, which are the current regulatory-approved versions. Nevada Energy's modeling used CALPUFF version 6.112, and CALMET version 6.211.

—Meteorological inputs: We used the meteorological inputs developed by the Western Regional Air Partnership, augmented with upper air data. Nevada Energy's modeling used some different inputs, and did not incorporate upper air data.

—SCR catalyst conversion efficiency: We performed our visibility modeling using an SCR catalyst SO_2 to SO_3 conversion efficiency of 0.5 percent for purposes of calculating sulfuric acid emissions. Nevada Energy's modeling relied upon 1 percent conversion efficiency.

—Calculation of visibility impact: We calculated our visibility impacts using the revised IMPROVE equation (Method 8, mode 5) [19] in addition to the original IMPROVE equation (Method 6). Nevada Energy's modeling was performed before the availability of modeling guidance regarding the use of the revised IMPROVE equation and its incorporation into CALPUFF as Method 8.

—Control technology performance: We performed our visibility modeling using the NO_X baseline emission rate and NO_X control technology emission rates listed under the ''NDEP'' column in Table 4, which had not previously been modeled.

—In addition, we modeled another SCR control technology case corresponding to a NO_X emission rate of 0.06 lb/MMBtu. As indicated in Table 4, both Nevada Energy and NDEP used control efficiency values in the range of 78 to 82 percent to estimate SCR performance. Typical SCR catalyst vendor guarantees can indicate 90 percent NO_X reduction.[20] We have elected to model 0.06 lb/MMBtu based on a selection of a mid-range control efficiency of 85 percent reduction from Nevada Energy's NO_X emission baseline.

A more detailed discussion of our visibility modeling, including full visibility results for all Class I areas located within 300 km of RGGS, is in our TSD and associated emission calculation spreadsheet. A summary of visibility results is presented in Table 5 below.

TABLE 5—SUMMARY OF VISIBILITY IMPACTS

Control option	Visibility Impact [1] (all three units) (dv)	Visibility improvement	
		From baseline (dv)	Incremental, from previous option (dv)
Baseline (LNB w/OFA)	0.59	....	....
LNB w/OFA (enhanced)	0.51	0.08	0.08
SNCR + LNB w/OFA	0.37	0.21	0.13
ROFA w/Rotamix	0.31	0.28	0.06
SCR w/LNB + OFA	0.22	0.36	0.09

[19] The IMPROVE equation translates modeled or monitored concentrations of pollutants like sulfate and nitrate into extinction, a measure of visibility. See: *http://vista.cira.colostate.edu/improve/ Extinction,* in turn, is used to calculate deciviews, the visibility impact metric used in the BART Guidelines. The various visibility ''methods'' in CALPUFF differ in how they account for background concentrations and adjustments for relative humidity. Method 8, mode 5 is the currently-recommended method. ''Federal Land Managers' Air Quality Related Values Workgroup (FLAG) Phase I Report'' (December 2000), U.S. Forest Service, National Park Service, U.S. Fish And Wildlife Service. See: *http://www.nature.nps.gov/air/Pubs/pdf/flag/FlagFinal.pdf.*

[20] We received public comments to this effect that included multiple vendor quotes. Available as attachments to Docket Items EPA–R09–OAR–2011–0130–0062 and –0063.

TABLE 5—SUMMARY OF VISIBILITY IMPACTS—Continued

Control option	Visibility Impact[1] (all three units) (dv)	Visibility improvement	
		From baseline (dv)	Incremental, from previous option (dv)
SCR w/LNB + OFA[2] (0.06 lb/MMBtu, each unit)	0.20	0.38	0.10

[1] Visibility impact summarized here represents the three-year 98th percentile impact at the Class I area with the highest impact, Grand Canyon National Park All three units were modeled together. The CALPUFF model output was post-processed using CALPOST visibility Method 8, the revised IMPROVE equation, and using natural background concentrations for the best 20% of days. For full visibility results, including impacts at other Class I areas within 300 km and using other visibility methods, please see the TSD in today's docket.
[2] Incremental visibility improvement compared to ROFA with Rotamix.

As seen in these results, the total incremental visibility improvement resulting from the installation of SCR with LNB and OFA compared to ROFA with Rotamix is 0.09 dv. This occurred at Grand Canyon National Park, the Class I area with the highest impact. In addition, we note that even our additional scenario that models the SCR control option at a 0.06 lb/MMBtu level of performance results in an incremental visibility improvement of only 0.10 dv relative to ROFA with Rotamix. Based on this small quantity of incremental visibility improvement, we agree with NDEP's conclusion that the control options more stringent than ROFA with Rotamix (or SNCR with LNB and OFA achieving the same emission limit) are not justified.

3. Existing Pollution Control Technology

NDEP's analysis: Nevada Energy prepared and submitted a BART analysis to NDEP that accounted for the presence of low-NO_X burners by using baseline NO_X emission factors corresponding to 2004 actual emissions data.[21] In preparing the RH SIP, NDEP developed a baseline NO_X emission factor that was based upon past actual emission data over a 2001–07 time frame.[22] This resulted in baseline NO_X emission rates that are approximately 15 percent higher than those presented in Nevada Energy's BART analysis.

EPA's analysis: While NDEP's use of a set of baseline emissions different from those presented in Nevada Energy's BART analysis does result in a higher baseline emission rate, NDEP's baseline emissions still reflect the use of low-NO_X burners. We find that NDEP's approach to this factor is reasonable, and have not modified NDEP's NO_X emission baseline in performing our own analysis. We do note that due to the emission calculation methodology NDEP used to calculate NO_X control scenario emissions, increases to the NO_X emission baseline will affect emission estimates for NO_X control scenarios. These effects are discussed further in the analysis of degree of visibility impact.

4. Remaining Useful Life of the Source

NDEP's analysis: In its BART analysis submittal to NDEP, Nevada Energy used a plant economic life of 20 years and performed control technology cost calculations based on control equipment lifetime equal to the plant economic life. In developing the RH SIP, NDEP relied upon these cost calculations without revision.

EPA's analysis: Use of a 20-year equipment life is consistent with assumptions made in EPA's Control Cost Manual for the equipment lifetime of certain NO_X control technologies such as SCR and SNCR. Commenters alleged that without a firm shutdown date to ensure a plant lifetime of 20 years, a longer equipment life should be used in cost calculations. Use of a longer equipment life would result in lower annualized costs, thereby making control technologies more cost effective. As discussed further in the analysis of costs of compliance, we already consider certain control technology options more stringent than ROFA with Rotamix, such as SCR with LNB and OFA, to be cost effective. As a result, we decline to pursue an analysis examining whether use of a 20-year plant economic life is appropriate.

5. Energy and Non-Air Quality Impacts

NDEP's Analysis: In its BART analysis submitted to NDEP, Nevada Energy identified certain energy impacts such as increased energy usage associated with ROFA as a result of induced draft fan installations. For SCR installations, increased energy usage is expected in order for existing fan systems to compensate for the additional pressure drop created by the SCR catalyst bed. Nevada Energy quantified these energy impacts as annual operating cost line items in cost calculations.

Non-air quality impacts identified by Nevada Energy in its BART analysis include the potential for ammonia slip from SCR or SNCR to impact the salability and disposal of fly ash, as well as to create a visible stack plume. The potential for transportation and storage of ammonia to result in an accidental release was also identified as a potential non-air quality impact. Nevada Energy cited these as negative impacts in its consideration of SCR and SNCR control options. In preparing the RH SIP, NDEP did not further expand on these impacts in determining ROFA with Rotamix as BART for NO_X.

EPA's Analysis: Although we consider the energy impacts accounted for by Nevada Energy to be reasonable, we note that supporting calculations were not provided for the line item cost associated with these impacts in control cost calculations. At this time, we decline to provide our own estimate of these impacts. Regarding non-air quality impacts, while we acknowledge that the items described by Nevada Energy are indeed potential concerns for the control technologies considered, we note that neither Nevada Energy's analysis nor the RH SIP provide further information discussing the extent to which these are site-specific concerns for RGGS Units 1 through 3. As a result, we consider these non-air quality impacts as not sufficiently significant at RGGS to warrant eliminating any of the control technology options.

VI. Federal Implementation Plan To Address NO_X BART for Reid Gardner

Although our analysis supports NDEP's decision to not require control technology options more stringent than ROFA with Rotamix (or SNCR with LNB and OFA achieving the same emissions

[21] Baseline emission factors as listed in Table 2–2 of each unit's respective Nevada Energy BART Analysis. Available as attachments to EPA–R09–OAR–2011–0130–0007.

[22] Per NDEP's Reid Gardner BART Determination Summary, NDEP used the average of the two consecutive years with highest annual emissions. Available as Docket Item No. EPA–R09–OAR–2011–0130–0005.

limit) as BART, completion of the BART process requires establishing enforceable emission limits that reflect the BART control technology requirements.[23] As described in the sections below, we find certain elements of the emission limits established for RGGS in the RH SIP as either unsupported by the record or inconsistent with BART Guidelines. NDEP notified us in a letter dated March 22, 2012 that it intends to submit a RH SIP revision that will address these elements, which include establishing a NO_X limit of 0.20 lb/MMBtu for Unit 3, and establishing NO_X limits for each unit on a 30-day rolling average (averaged across all three units), rather than a 12-month rolling average. In addition, NDEP has indicated that the RH SIP revision it intends to submit will revise the selected control technology from ROFA with Rotamix to SNCR with LNB and OFA.

In order to meet the terms of our consent decree, it is necessary for EPA to propose action on Nevada's RH SIP at this time. As a result, we are proposing the promulgation of a FIP that will address the elements described below. We expect these elements to match the content of the revised RH SIP that Nevada has indicated it intends to submit.

Based upon the March 22, 2012 letter sent by NDEP indicating its intent to submit a revised RH SIP, we do not expect to receive the revised RH SIP prior to our consent decree deadline for final action on this proposal. Although we will not receive the revised RH SIP prior to our final action, we do intend to act expeditiously on the revised RH SIP once it is submitted to EPA.

A. Unit 1 Through 3 Averaging Period

We are proposing to promulgate a FIP to establish a NO_X emission limit of 0.20 lb/MMBtu for Unit 3. In its RH SIP, NDEP proposed a NO_X emission limit of 0.28 lb/MMBtu for Unit 3. This limit for Unit 3 (0.28 lb/MMBtu) was higher than the emission limit NDEP proposed for Units 1 or 2 (0.20 lb/MMBtu each). The higher emission limit appears to be partially attributable to the fact that the application of control technology to Unit 3 was projected to result in less stringent levels of performance relative to Units 1 and 2. As shown in Table 4 of this notice, Nevada Energy's emission estimates indicate that application of ROFA with Rotamix achieves nearly 60 percent reduction from baseline on Units 1 and 2, but only a 38 percent reduction from baseline on Unit 3. These percent reduction values were used by NDEP in developing its own estimate of NO_X emissions, which form the basis for the proposed NO_X limits.

Nevada Energy's BART analysis for Unit 3 did not provide a unit-specific explanation for this difference in control effectiveness. In responding to comments on this issue, NDEP indicated that it deferred to Nevada Energy's operational experience in developing control efficiency data, and had no reason to question Nevada Energy's estimates.[24] The case-by-case nature of the BART determination process does provide for the consideration of site-specific and unit-specific characteristics in the BART analysis.[25] While there may be unique characteristics associated with Unit 3 that justify the lower percent reduction values used by Nevada Energy and NDEP, we do not find the record on this issue to be sufficiently detailed to support this determination. In the absence of what we consider sufficient justification by Nevada Energy and NDEP, we have evaluated Unit 3 control option emissions predicated upon similar levels of performance relative to Units 1 and 2. Based upon the Unit 3 baseline emissions relied upon by NDEP (described in the 'NDEP' column in Table 4), if a percent reduction similar to Units 1 and 2 were applied to Unit 3 baseline emissions, it can be expected to attain a NO_X emission rate of 0.20 lb/MMBtu using the ROFA with Rotamix control option.

B. Unit 3 Emission Limit

We are proposing to promulgate a FIP to establish a 30-day rolling average, averaged across all three units, as the basis for the NO_X emission limits for RGGS Units 1 through 3. In its RH SIP, NDEP proposed NO_X limits for Units 1 through 3 based upon a 12-month rolling average, which is a longer averaging period than the 30-day rolling average indicated by the BART Guidelines. Longer averaging periods allow operators the flexibility to ''smooth out'' short-term emission spikes by averaging those values with periods of lower emission rates. In responding to comments on this issue in its RH SIP, NDEP indicated that it specified the longer averaging period because Nevada Energy expected a high degree of operational variability with the ROFA with Rotamix control option based upon previous operational experience with ROFA.[26] Although operational flexibility can be a legitimate consideration when establishing an enforceable limit, we consider use of a rolling 12-month averaging period instead of a rolling 30-day average to be inconsistent with BART Guidelines.[27] We believe the fluctuations of the NO_X emissions from each of the units is better dealt with by averaging the emissions from the three units to determine compliance over the 30-day rolling average.

C. Control Technology Basis

In its RH SIP, NDEP proposed emission limits for Units 1 through 3 based upon a control technology determination of ROFA with Rotamix. In its March 22, 2012 letter, NDEP indicated that it intends to submit an RH SIP revision that will revise the control technology determination to SNCR with LNB and OFA. In addition, the corresponding BART emission limits for NO_X that NDEP has indicated it will establish for Units 1 through 3 are of equal or greater stringency than those included in the current RH SIP.

In its RH SIP, NDEP estimated that SNCR with LNB and OFA would be capable of achieving a NO_X emission rate in the range of 0.27 to 0.31 lb/MMBtu (as summarized in Table 1 of this notice). These emission rates indicate that the SNCR with LNB and OFA control option is less stringent than ROFA with Rotamix, which NDEP estimated would be capable of achieving a NO_X emission rate in the range of 0.20 to 0.28 lb/MMBtu. As noted in the BART Guidelines, BART ''means an emission limitation based on the degree of reduction achievable through the application of the best system of continuous emission reduction.'' [28] Although NDEP may propose a less stringent control technology determination in a future RH SIP revision, we would not consider the final BART determination to be less stringent if the selected control option is capable of meeting the NO_X emission limit of 0.20 lb/MMBtu (30-day rolling average, averaged across all three units) established in our FIP.

VI. Federal Implementation Plan To Address NO_X BART for Reid Gardner

With the exception of the NO_X BART emission limit for Unit 3 and the NO_X averaging time for all three units, EPA is proposing to find the Nevada RH BART determination for NO_X fulfills all

[23] 70 FR 39172.

[24] Page D–37, Appendix D and C–9, Appendix C, Nevada RH SIP. Available as attachments to EPA–R09–OAR–2011–0130–0003.

[25] For example, when determining what control options are considered technically feasible at a specific unit, 70 FR 39165.

[26] Page D–60, Appendix D, Nevada RH SIP. Available as attachments to EPA–R09–OAR–2011–0130–0003.

[27] 70 FR 39172.

[28] 70 FR 39163.

the relevant requirements of CAA Section 169A and the Regional Haze Rule. Therefore, we are proposing to approve NDEP's conclusion that SCR is not required as BART for NO_X. NDEP weighed the incremental cost of requiring SCR against the relatively small visibility improvement that would be achieved from installing and operating SCR. NDEP's incremental cost included costs that inappropriately increased the cost estimate. However, NDEP is allowed to weigh the incremental cost against the incremental visibility improvement. Our independent modeling found that incremental visibility improvement at adjacent Class I areas would be significantly lower than the improvement modeled by NDEP. This information supports our determination that NDEP is within the discretion allowed by the BART Guidelines to establish the NO_X emissions limit that can be achieved with ROFA and Rotamix (or SNCR with LNB and OFA achieving the same emissions limit) as BART rather than requiring an emission limit consistent with SCR technology.

NDEP, however, failed to support applying a higher emission limit for Unit 3 and failed to provide a sufficient basis for approving the emissions limit on a 12-month rolling average. Therefore, EPA is disapproving the RGGS NO_X BART determination for Unit 3 and promulgating a FIP setting the same emission limit for Unit 3 that NDEP set for Units 1 and 2. EPA is also promulgating a FIP requiring Units 1 through 3 to meet the NO_X emissions limit of 0.20 lbs/mmbtu on a rolling 30-day average (across all three units).

VII. EPA's Proposed Action

A. Executive Order 12866: Regulatory Planning and Review

This proposed action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), and is therefore not subject to review under the Executive Order. The proposed FIP applies to only one facility and is therefore not a rule of general applicability.

B. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. Under the Paperwork Reduction Act, a ''collection of information'' is defined as a requirement for ''answers to * * * identical reporting or recordkeeping requirements imposed on ten or more persons * * *.'' 44 U.S.C. 3502(3)(A). Because the proposed FIP applies to just one facility, the Paperwork Reduction Act does not apply. See 5 CFR 1320(c).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control numbers for our regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed action on small entities, I certify that this proposed action will not have a significant economic impact on a substantial number of small entities. The Regional Haze FIP for the single facility being proposed today does not impose any new requirements on small entities. The proposed partial approval of the SIP, if finalized, merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. See *Mid-Tex Electric Cooperative, Inc.* v. *FERC,* 773 F.2d 327 (D.C. Cir. 1985)

D. Unfunded Mandates Reform Act (UMRA)

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more (adjusted to inflation) in any 1 year. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

Under Title II of UMRA, EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures that exceed the inflation-adjusted UMRA threshold of $100 million by State, local, or Tribal governments or the private sector in any 1 year. In addition, this proposed rule does not contain a significant Federal intergovernmental mandate as described by section 203 of UMRA nor does it contain any regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely addresses elements of the State's Regional Haze SIP that are inconsistent with the Regional Haze Rule. In addition, the State has indicated that it intends to submit a SIP revision, the contents of which are intended to match the content of the FIP proposed in this rule. Thus, Executive Order 13132 does not apply to this action. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' We note that the SIP is not approved to apply in Tribal lands located in the State, will not impose substantial direct costs on tribal governments or preempt tribal law, and does not affect the distribution of power and responsibilities between the Federal Government and any Indian tribes. As a result, while this rule applies to an emissions source that is adjacent to the Moapa Reservation, it does not have direct tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). However, we acknowledge that concerns about the environmental impacts of this facility have been raised by the Moapa Tribe. We have formally consulted with the Moapa Tribe regarding those concerns, and have visited the reservation and the facility. We will continue to work with the Moapa Tribe as we proceed with our action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be economically significant as defined under Executive Order 12866; and (2) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks. However, to the extent this proposed rule will limit emissions of NO_X, the rule will have a beneficial effect on children's health by reducing air pollution.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical. The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

VIII. Statutory and Executive Order Reviews

Executive Order 12898 (59 FR 7629, February 16, 1994), establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. We have determined that this proposed rule, if finalized, will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This proposed rule limits emissions of NO_X from a single facility in Nevada. The partial approval of the SIP, if finalized, merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen oxides, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 2, 2012.

Jared Blumenfeld,

Regional Administrator, Region 9.

For the reasons stated in the preamble, Part 52, chapter I, title 40 of the Code of Federal Regulations is proposed to be amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Part 52 is amended by adding § 52.1488(e) to 52.1488 Visibility Protection, to read as follows:

§ 52.1488 Visibility protection.

* * * * *

(e) This paragraph (e) applies to each owner and operator of the coal-fired electricity generating units (EGUs) designated as Units 1, 2, and 3 at the Reid Gardner Generating Station in Clark County, Nevada.

(1) *Definitions.* Terms not defined below shall have the meaning given to them in the Clean Air Act or EPA's regulations implementing the Clean Air Act. For purposes of this section:

Ammonia injection shall include any of the following: anhydrous ammonia, aqueous ammonia or urea injection.

Combustion controls shall mean new low NO_X burners, new overfire air, and/or rotating overfire air.

Continuous emission monitoring system or *CEMS* means the equipment required by 40 CFR Part 75 to determine compliance with this section.

NO_X means nitrogen oxides expressed as nitrogen dioxide (NO_2).

Owner/operator means any person who owns or who operates, controls, or supervises an EGU identified in paragraph (e) of this section.

Unit means any of the EGUs identified in paragraph (e) of this section.

Unit-wide means all of the EGUs identified in paragraph (e) of this section.

(2) *Emission limitations*—The NO_X limit, expressed as nitrogen dioxide, for Units 1, 2, and 3 shall be 0.20 lb/MMBtu based on a unit-wide heat input weighted average determined over a rolling 30-calendar day period. NO_2 emissions for each calendar day shall be determined by summing the hourly emissions measured in pounds of NO_2 for all operating units. Heat input for each calendar day shall be determined by adding together all hourly heat inputs, in millions of BTU, for all operating units. Each day the thirty-day rolling average shall be determined by adding together that day and the preceding 29 days' pounds of NO_2 and dividing that total pounds of NO_2 by the sum of the heat input during the same 30-day period. The results shall be the 30-calendar day rolling pound per million BTU emissions of NO_2.

(3) *Compliance date.* The owners and operators subject to this section shall comply with the emissions limitations and other requirements of this section within 5 years from promulgation of this paragraph and thereafter.

(4) *Testing and Monitoring.* (i) The owner or operator shall use 40 CFR Part 75 monitors and meet the requirements found in 40 CFR Part 75. In addition to these requirements, relative accuracy test audits shall be performed for both the NO_2 pounds per hour measurement and the hourly heat input measurement, and shall have relative accuracies of less than 20%. This testing shall be evaluated each time the 40 CFR Part 75 monitors undergo relative accuracy testing. Compliance with the emission limit for NO_2 shall be determined by using data that is quality assured and considered valid under 40 CFR Part 75, and which meets the relative accuracy of this paragraph.

(ii) If a valid NO_X pounds per hour or heat input is not available for any hour for a unit, that heat input and NO_X pounds per hour shall not be used in the calculation of the unit-wide rolling 30-calendar day average. Each Unit shall obtain at least 90% valid hours of data over each calendar quarter. 40 CFR Part 60 Appendix A Reference Methods may be used to supplement the Part 75 monitoring.

(iii) Upon the effective date of the unit-wide NO_X limit, the owner or operator shall have installed CEMS software that meets with the requirements of this section for measuring NO_2 pounds per hour and calculating the unit-wide 30-calendar day rolling average as required in paragraph (e)(2) of this section.

(iv) Upon the completion of installation of ammonia injection on any of the three units, the owner or operator shall install, and thereafter maintain and operate, instrumentation to continuously monitor and record levels of ammonia consumption for that unit.

(5) *Notifications.* (i) The owner or operator shall notify EPA within two weeks after completion of installation of combustion controls or ammonia injection on any of the units subject to this section.

(ii) The owner or operator shall also notify EPA of initial start-up of any equipment for which notification was given in paragraph (e)(5)(i).

(6) *Equipment Operations.* After completion of installation of ammonia injection on any of the three units, the owner or operator shall inject sufficient ammonia to minimize the NO_X emissions from that unit while preventing excessive ammonia emissions.

(7) *Recordkeeping.* The owner or operator shall maintain the following records for at least five years:

(i) For each unit, CEMS data measuring NO_X in lb/hr, heat input rate per hour, the daily calculation of the unit-wide 30-calendar day rolling lb NO_2/MMbtu emission rate as required in paragraph (e)(2) of this section.

(ii) Records of the relative accuracy test for NO_X lb/hr measurement and hourly heat input

(iii) Records of ammonia consumption for each unit, as recorded by the instrumentation required in paragraph (e)(4)(iv) of this section.

(8) *Reporting.* Reports and notifications shall be submitted to the Director of Enforcement Division, U.S. EPA Region IX, at 75 Hawthorne Street, San Francisco, CA 94105. Within 30 days of the end of each calendar quarter after the effective date of this section, the owner or operator shall submit a report that lists the unit-wide 30-calendar day rolling lb NO_2/MMBtu emission rate for each day. Included in this report shall be the results of any relative accuracy test audit performed during the calendar quarter.

(9) *Enforcement.* Notwithstanding any other provision in this implementation plan, any credible evidence or information relevant as to whether the unit would have been in compliance with applicable requirements if the appropriate performance or compliance test had been performed, can be used to establish whether or not the owner or operator has violated or is in violation of any standard or applicable emission limit in the plan.

[FR Doc. 2012–8713 Filed 4–11–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2009–0882; FRL–9656–9]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Streamlining Amendments to the Plan Approval Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to grant limited approval to a State Implementation Plan (SIP) revision submitted by the Pennsylvania Department of Environmental Protection (PADEP) on April 14, 2009. The revision pertains to PADEP's plan approval requirements for the construction, modification, and operation of sources, and is primarily intended to streamline the process for minor permitting actions. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before May 14, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2009–0882 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: cox.kathleen@epa.gov.*

C. *Mail:* EPA–R03–OAR–2009–0882, Kathleen Cox, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2009–0882. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: David Talley, (215) 814–2117, or by email at *talley.david@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. On April 14, 2009, PADEP submitted revisions to its State Implementation Plan (SIP). The proposed revisions consist of amendments to the plan approval requirements for the construction, modification, reactivation, and operation of sources.

Table of Contents

I. Background

Generally speaking, anyone constructing or operating a source in Pennsylvania that emits pollutants into the air must comply with the general requirement to obtain a ''plan approval'' prior to construction as outlined in 25 Pa. Code 127, Subchapters A and B. These subchapters are generally considered the state's minor New Source Review (NSR) program covering minor sources as well as minor changes at major sources. Major sources are subject to the additional requirements of subchapters D Prevention Significant Deterioration (PSD) and E (nonattainment NSR). Subchapter E also includes additional provisions relating to minor changes at major sources for ozone precursors Nitrogen Oxides and Volatile Organic Compounds (NOx and VOCs). A plan approval is a permit that authorizes construction, installation, or modification of any air pollution source. In evaluating the plan approval application, PADEP checks to see that both the operation of the source and the control equipment installed to reduce air pollution meet the applicable technical and engineering requirements. The public is given an opportunity to comment on the plan approval application. In addition to being a permit to construct, the plan approval provides temporary authorization for the source to operate to assure that the equipment functions properly. This temporary authorization is known as the ''shakedown'' period.

The plan approval regulations that are the subject of this proposed action are codified at 25 Pa. Code 127, Subchapter B (relating to general requirements for all plan approvals). EPA last took action on these provisions on July 30, 1996. Pennsylvania adopted the amendments being proposed in this action, and published notice of final rulemaking in the *Pennsylvania Bulletin* on May 24, 2008. The primary purpose of the amendments is to streamline the permitting process by eliminating some of the administrative burden and costs associated with processing minor permitting actions, while preserving the right of the public to review and comment on those proposed actions. The proposed amendments generally affect five regulations: Section 127.12b, pertaining to ''shakedown'' periods for new or modified sources; section 127.12d, pertaining to completeness determinations; sections 127.44 and 127.45, pertaining to public notice requirements; and section 127.48, pertaining to conferences and hearings. The specific revisions are discussed in detail below.

II. Summary of SIP Revision

A. 25 Pa. Code 127.12b: Plan Approval Terms and Conditions

Section 127.12b(d), as approved by EPA on July 30, 1996, authorizes a temporary ''shakedown'' period for new and modified sources and air cleaning equipment for a period of 180 days pending issuance of a state operating permit or a Title V permit, ''* * * to permit the evaluation of the air contamination aspects of the source'' (see section 127.12b(d)). The regulation as currently approved in Pennsylvania's SIP also allows for limited extensions of this period, with each extension limited to 120 days. The proposed revision increases the permissible duration of the extensions to 180 days.

B. 25 Pa. Code 127.12d: Completeness Determination

The proposed revisions incorporate new requirements into the Pennsylvania SIP that outline PADEP's obligations with respect to determining whether an applicant has submitted an administratively complete application, and notifying the applicant of that decision. These requirements are codified at section 127.12d(a) thru (c). Section 127.12d(a) requires PADEP to make a completeness determination and provide notice to the applicant within 30 days of receipt of the application. Section 127.12d(b) establishes guidelines for what constitutes an administratively complete application.

In the event an application is deemed to be incomplete, section 127.12d(c) requires PADEP to notify the applicant of the specific deficiency, and to return the application and fees to the applicant if the requested information is not submitted within ten (10) working days of being notified by PADEP that the application is incomplete. These regulations as proposed by PADEP are consistent with CAA requirements, and are in fact more prescriptive than their Federal counterparts at 40 CFR 51.166(q)(1).

C. 25 Pa. Code 127.44: Public Notice and 25 Pa. Code 127.45: Contents of Notice

The public notice requirements of section 127.44 as currently approved in the Pennsylvania SIP make no distinction between major and minor permitting actions—the requirements are the same. Pennsylvania adopted the proposed revisions to the public notice requirements of section 127.44 (and 127.45, below) in an effort to streamline the process for minor permitting actions and allow PADEP to focus its limited resources on major permitting actions.

In the current SIP, section 127.44 sections (a)(1) thru (6) list the types of plan approvals for which the public notice requirements apply. These include section (a)(5): ''Other sources required to obtain plan approval,'' which has the effect of applying the notice requirements to all plan approval actions equally. Pennsylvania has a robust minor New Source Review (NSR) program. Very few sources escape the requirement to obtain a plan approval, and every plan approval is subject to public notice requirements. Prior to these revisions, significant time and resources were being spent on relatively minor permitting actions. The proposed revisions involve the bifurcation of the notice requirements into a new section 127.44(a) which applies to minor actions, and a new section 127.44(b) which applies to major actions as well as any action for which PADEP determines that significant public interest exists. The remaining unchanged sections were re-ordered sequentially to allow for the bifurcation.

Pursuant to the proposed amendments, under the revised section 127.44(a) PADEP will publish a ''notice of receipt and intent to issue'' in the *Pa. Bulletin* for each plan approval application relating to a minor permitting action. PADEP has, as a policy, generally published two notices for all plan approval actions: one upon receipt of an application, and one of intent to issue a proposed plan approval. Under the proposed revisions, proposed plan approval actions that are subject to section 127.44(a) will be issued at the end of the public comment period without further notice, unless significant public comments are received. The notice requirements for major actions, now at section 127.44(b), were not substantively amended. We read the requirements of section 127.44(f) to apply to all plan approvals that are subject to section 127.44. These include the requirement that the application materials be made available for review in the region affected by the project, and that a 30-day public comment period be established (127.44(f)(1) and (f)(2) respectively).

In the proposed revisions, section 127.45 was similarly bifurcated to incorporate separate requirements for minor and major actions. As with the notice requirements of section 127.44, the content requirements of section 127.45 for permitting actions considered by PADEP to be major, (now at 127.45(b)), were not substantively modified. For minor actions, section 127.45(a) outlines what must be included in each ''notice of receipt and intent to issue.'' These requirements include: the name and address of the applicant and the location of the source, a brief discussion of the proposed action including a description of the source, the control technology, the conditions being placed in the permit, and the type and quantity of air contaminants being emitted, as well as a point of contact at PADEP, and the statement that a person may oppose the proposed plan approval by filing a written protest with the appropriate regional office (see proposed section 127.45(a)). The requirements for minor permitting actions under this section do not vary significantly from the requirements for major actions. The primary differences are that section 127.45(b) requires a description of increment consumption (where applicable), and a description of the procedures for reaching a final decision on the proposed plan approval, including the end date for receipt of written protests, procedures for requesting a hearing, and other procedures for public involvement in the final decision (see proposed section 127.45(b)(6)). The result of the proposed revisions to sections 127.44 and 127.45 is that for minor permitting actions, public notice of the proposed action will be less detailed than for major actions, will be provided once, and only in the *Pa. Bulletin* (which publishes online and in print).

The Federal requirements with regard to public availability of information are codified at 40 CFR 51.161. Specifically, 40 CFR 51.161(a) requires that ''[t]he public information must include the agency's analysis of the effect of construction or modification on ambient air quality, including the agency's proposed approval or disapproval.'' EPA believes that to some extent, the intent of section 51.161(a) was met in sections 127.45(a)(3) and (4) of Pennsylvania's proposed SIP revision, which discuss the content of the public notice. These sections require a description of the proposed construction or modification, the control technology being installed, the conditions in the proposed permit (with reference to applicable federal requirements), and the type and quantity of air contaminants being emitted. Nevertheless, the agency analysis required by 40 CFR 51.161(a) is not explicitly required in the proposed SIP revision, nor do the regulations of sections 127.44 and 127.45 require that the agency's analysis be made available for public inspection in at least one location, in accordance with 40 CFR 51.161(b)(1). Section 127.44(f)(1) requires only that the application be made available. Therefore, EPA is proposing to grant limited approval to PADEP's proposed revision. To receive full approval, PADEP must adopt the explicit requirement that the agency's analysis be included in the information provided to the public for comment pursuant to 40 CFR 51.161(a), as well as the requirement that the analysis be made available for public inspection pursuant to 40 CFR 51.161(b)(1), and submit those changes to EPA as a formal SIP revision.

D. 25 Pa. Code 127.48: Conferences and Hearings

The regulations at section 127.48 contain the requirements regarding public hearings or fact finding conferences on proposed plan approvals. The PADEP may, at its discretion, hold such a hearing when it is deemed necessary due to sufficient public impact or interest. The proposed amendments to section 127.48(b) include some clarifying language regarding hearing notices. More substantively, the amendments include the requirement to publish notice ''* * * in a newspaper of general circulation in the county in which the source is to be located * * *''. The current SIP only requires that the notice be published in the *Pa. Bulletin* or a newspaper. The regulations as amended in the proposed SIP revision require both, and as such represent a strengthening of the SIP.

III. Proposed Action

EPA's review of this material indicates that with the one noted exception, the proposed revisions to 25 Pa. Code 127, Subchapter B meet or exceed Federal requirements. EPA is proposing to grant limited approval to the Pennsylvania SIP revision, which was submitted on April 14, 2009. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action regarding streamlining amendments to Pennsylvania's plan approval process does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 28, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2012–8852 Filed 4–11–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0244; FRL–9657–9]

Approval and Promulgation of Implementation Plans; State of Arizona; Prevention of Air Pollution Emergency Episodes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the State Implementation Plan (SIP) revision submitted by the State of Arizona to address the requirements regarding air pollution emergency episodes in Clean Air Act (CAA or Act) section 110(a)(2)(G). Section 110(a)(2)(G) of the Act requires that each SIP provide for authority comparable to that in section 303 of the Act and adequate contingency plans to implement such authority. EPA is proposing to approve Arizona's SIP revision as meeting the authority and contingency plans for the 1997 8-hour ozone National Ambient Air Quality Standards (NAAQS or standards).

DATES: Written comments must be received on or before May 14, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2012–0244, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: buss.jeffrey@epa.gov.*
3. *Fax:* 415–947–3579.
4. *Mail or deliver:* Jeffrey Buss (AIR–2), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 947–4152, *buss.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms "we," "us," and "our" refer to EPA.

Table of Contents

I. Background

On July 18, 1997, EPA promulgated revised primary and secondary NAAQS for ozone which set the acceptable level of ozone in the ambient air at 0.08 parts per million (ppm), averaged over an 8-hour period. 62 FR 38856; 40 CFR 50.10. This proposed action is in response to the promulgation of these ozone standards.

Section 110(a)(1) of the CAA requires states to submit SIPs to address a new or revised NAAQS within three years after promulgation of such standards, or within such shorter period as EPA may prescribe. Section 110(a)(2) lists the elements that these SIPs must address, as applicable, including section 110(a)(2)(G) regarding authority to address air pollution emergency episodes and adequate contingency plans to implement such authority (Emergency Episode Plans). EPA last approved an Emergency Episode Plan requirement into the Arizona SIP on September 28, 1982 (47 FR 42572).

On October 2, 2007, EPA issued a guidance memorandum that provides recommendations to states for making submissions to meet, among other things, the requirements of section 110(a)(2)(G) for the 1997 8-Hour ozone standards. *See* Memorandum from William T. Harnett, EPA Air Quality Policy Division, to Air Division Directors, Regions I–X, ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' October 2, 2007 (2007 Guidance).

This proposed action addresses only Arizona's submittal to satisfy the Emergency Episode Plan requirements of CAA section 110(a)(2)(G) and does not apply to the remaining ''infrastructure'' SIP elements of CAA section 110(a)(2) for the 1997 8-hour ozone NAAQS. We intend to evaluate and act upon Arizona's SIP submittal addressing these additional requirements of CAA section 110(a)(2) for the 1997 8-hour ozone NAAQS in separate actions.

II. EPA's Evaluation of the SIP Revision

A. SIP Procedural Requirements

CAA sections 110(a)(1) and (2) and section 110(l) require that each revision to a SIP be adopted by the state after reasonable notice and public hearing. EPA has promulgated specific procedural requirements for SIP revisions in 40 CFR part 51, subpart F. These requirements include publication of notices, by prominent advertisement in the relevant geographic area, of a public hearing on the proposed revisions, a public comment period of at least 30 days, and an opportunity for a public hearing.

On August 15, 1994, the Arizona Department of Environmental Quality (ADEQ) submitted section 220 of Chapter 2, Title 18 of the Arizona Administrative Code (R18–2–220), ''Air pollution emergency episodes'' (hereafter referred to as ''Arizona Emergency Episode Plan'') to EPA for approval as part of the Arizona SIP.[1] ADEQ's August 15, 1994 submittal includes public process documentation for the Arizona Emergency Episode Plan, among other regulations. In addition, the SIP revision includes documentation of a duly noticed public hearing held on August 9, 1994 on the proposed version of the Arizona Emergency Episode Plan. We find that the process followed by ADEQ in adopting the Arizona Emergency Episode Plan complies with the procedural requirements for SIP revisions under CAA section 110 and EPA's implementing regulations.

B. Substantive Emergency Episode Plan Requirements

Section 110(a)(2)(G) of the CAA requires that each SIP provide for authority comparable to that in CAA section 303 (''Emergency Powers'') and adequate contingency plans to implement such authority. EPA's implementing regulations in 40 CFR part 51, subpart H (''Prevention of Air Pollution Emergency Episodes''), establish a ''priority'' classification system under which each region in a state is classified separately for each of the following criteria pollutants, based on ambient concentrations of the pollutant: sulfur dioxide (SO_2), particulate matter of 10 microns or less (PM_{10}), carbon monoxide (CO), nitrogen dioxide (NO_2), and ozone. Subpart H specifies the requirements that each contingency plan must meet, based on the priority classification of the area in which it applies. *See* 40 CFR 51.152. Subpart H also requires that each contingency plan for a ''priority I'' area provide, at a minimum, for taking action necessary to prevent ambient pollutant concentrations at any location in such region from reaching specified ''significant harm levels'' (SHL). 40 CFR 51.151. The SHL for ozone is 1,200 micrograms per cubic meter ($\mu g/m^3$) or 0.6 ppm over a 2-hour average. *Id.*

EPA's 2007 Guidance addressed, among other things, the CAA section 110(a)(2)(G) requirements for the 1997 8-hour ozone NAAQS. The 2007 Guidance stated that the SHL for the 1997 8-hour ozone NAAQS would remain unchanged as 0.60 ppm over a 2-hour average, as indicated in 40 CFR section 51.151, and that the existing ozone-related provisions of 40 CFR part 51, subpart H remained appropriate for purposes of implementing the 1997 8-hour ozone standard. *See* 2007 Guidance at 5. We have evaluated the Arizona Emergency Episode Plan in accordance with the requirements of 40 CFR part 51, subpart H, as applicable for ozone purposes, consistent with EPA's recommendations in the 2007 Guidance. Based on this evaluation, we propose to fully approve the Arizona Emergency Episode Plan as satisfying the requirements of CAA section 110(a)(2)(G) and 40 CFR part 51, subpart H, for the 1997 8-hour ozone NAAQS. Our technical support document (TSD), which is available in the docket for today's proposed rule, contains a more detailed discussion of our evaluation.

C. Sections 110(l) and 193 of the Act

Section 110(l) of the Act prohibits EPA from approving any SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress (RFP) or any other applicable requirement of the Act. Section 193 of the Act prohibits the modification, in a nonattainment area, of any SIP-approved control requirement in effect before November 15, 1990, unless the modification ''insures equivalent or greater emissions reductions of such air pollutant.''

The Arizona Emergency Episode Plan is substantively identical to the CAA section 110(a)(2)(G) rule currently approved into Arizona's SIP (R9–3–219, ''Air pollution emergency episodes''), which EPA approved in 1982 (47 FR 42572, September 28, 1982), with one exception which makes it more stringent than the SIP program. We propose to determine that our approval of this submittal would comply with CAA section 110(l), because the proposed SIP revision would not interfere with the ongoing process for

[1] See transmittal letter dated August 15, 1994, from Edward Z. Fox, Director, ADEQ, to Felicia Marcus, Regional Administrator, U.S. EPA Region IX, with attachments. We note that although the subject line of the transmittal letter identifies this SIP submittal as related to ''New Source Review and Prevention of Significant Deterioration (NSR/PSD) Program for Major Sources and Major Modifications and New Source Review (NSR) for Minor Sources,'' Attachment 6 of this submittal includes the Arizona Emergency Episode Plan, which is not related to NSR or PSD.

ensuring that requirements for RFP and attainment of the NAAQS are met, and the submitted SIP revision is more stringent than the rule previously approved into the SIP. We also propose to determine that our approval of the submittal would comply with CAA section 193, to the extent it applies, because the SIP revision would insure equivalent or greater emission reductions of ozone precursors compared to the SIP-approved rule. Our TSD contains a more detailed discussion of our evaluation.

III. EPA's Proposed Action

Under section 110(k) of the Clean Air Act, EPA is proposing to approve the SIP revision submitted by ADEQ on August 15, 1994, as meeting all applicable requirements of the CAA and EPA's regulations for the 1997 8-hour ozone NAAQS.

EPA is soliciting public comments on this proposal and will accept comments until the date noted in the **DATES** section above.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Air pollution control, Environmental protection, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 29, 2012.

Keith Takata,

Acting Regional Administrator, Region IX.

[FR Doc. 2012–8837 Filed 4–11–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0228; FRL–9657–5]

Approval and Promulgation of State Implementation Plans; Hawaii; Infrastructure Requirements for the 1997 8-Hour Ozone and the 1997 and 2006 Fine Particulate Matter National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to partially approve and partially disapprove a State Implementation Plan (SIP) revision submitted by the State of Hawaii pursuant to the requirements of Section 110(a)(1) and (2) of the Clean Air Act (CAA) for the 1997 8-hour ozone national ambient air quality standards (NAAQS) and the 1997 and 2006 NAAQS for fine particulate matter ($PM_{2.5}$). Section 110(a) of the CAA requires that each State adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by the EPA. On December 14, 2011, the Hawaii Department of Health (HDOH) submitted a revision to Hawaii's SIP, which describes the State's provisions for implementing, maintaining, and enforcing standards listed above. We are taking comments on this proposal and plan to follow with a final action.

DATES: Written comments must be received on or before May 14, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2012–0228, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: richmond.dawn@epa.gov.*
3. *Fax:* 415–947–3579.
4. *Mail or deliver:* Dawn Richmond, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed directly below.

FOR FURTHER INFORMATION CONTACT: Dawn Richmond, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3207, *richmond.dawn@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to EPA.

Table of Contents

I. Background

A. Statutory Framework

Section 110(a)(1) of the CAA requires states to make a SIP submission ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' that provides for the ''implementation, maintenance, and enforcement'' of such NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must meet. Many of the section 110(a)(2) SIP elements relate to the general information and authorities that constitute the ''infrastructure'' of a state's air quality management program and SIP submittals that address these requirements are referred to as ''infrastructure SIPs.'' These infrastructure SIP elements include:

• Section 110(a)(2)(A): Emission limits and other control measures.
• Section 110(a)(2)(B): Ambient air quality monitoring/data system.
• Section 110(a)(2)(C): Program for enforcement of control measures and regulation of new stationary sources.
• Section 110(a)(2)(D)(i): Interstate pollution transport.
• Section 110(a)(2)(D)(ii): Interstate and international pollution abatement.
• Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
• Section 110(a)(2)(F): Stationary source monitoring and reporting.
• Section 110(a)(2)(G): Emergency episodes.
• Section 110(a)(2)(H): SIP revisions.
• Section 110(a)(2)(J): Consultation with government officials, public notification, and prevention of significant deterioration (PSD) and visibility protection.
• Section 110(a)(2)(K): Air quality modeling and submission of modeling data.
• Section 110(a)(2)(L): Permitting fees.
• Section 110(a)(2)(M): Consultation/participation by affected local entities.

Two elements identified in section 110(a)(2) are not governed by the three-year submission deadline of section 110(a)(1) and are therefore not addressed in this action. These elements relate to part D of title I of the CAA, and submissions to satisfy them are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the same time nonattainment area plan requirements are due under section 172. The two elements are: (i) Section 110(a)(2)(C) to the extent it refers to permit programs required under part D (nonattainment New Source Review (NSR)), and (ii) section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure elements related to the nonattainment NSR portion of section 110(a)(2)(C) or related to 110(a)(2)(I).

B. Regulatory History

On July 18, 1997, EPA issued a revised NAAQS for ozone [1] and a new NAAQS for fine particulate matter ($PM_{2.5}$).[2] EPA subsequently revised the 24-hour $PM_{2.5}$ NAAQS on September 21, 2006.[3] Each of these actions triggered a requirement for States to submit an infrastructure SIP to address the applicable requirements of section 110(a)(2) within three years of issuance of the new or revised NAAQS.

On March 10, 2005, EPA entered into a Consent Decree with Earthjustice that obligated EPA to make official findings in accordance with section 110(k)(1) of the CAA as to whether States had made required complete SIP submissions, pursuant to sections 110(a)(1) and (2), by December 15, 2007 for the 1997 8-hour ozone NAAQS and by October 5, 2008 for the 1997 $PM_{2.5}$ NAAQS. EPA made such findings for the 1997 8-hour ozone NAAQS on March 27, 2008 (73 FR 16205) and on October 22, 2008 (73 FR 62902) for the 1997 $PM_{2.5}$ NAAQS. In each case, EPA found that Hawaii had failed to make a complete submittal to satisfy the requirements of section 110(a)(2) for the relevant pollutant. On September 8, 2011, EPA made a similar finding of failure to submit for Hawaii in relation to the 2006 24-hour $PM_{2.5}$ NAAQS (76 FR 55577).[4]

C. Scope of the Infrastructure SIP Evaluation

EPA is currently acting upon SIPs that address the infrastructure requirements of CAA section 110(a)(1) and (2) for ozone and $PM_{2.5}$ NAAQS for various states across the country. Commenters on EPA's recent proposals for some states raised concerns about EPA statements that it was not addressing certain substantive issues in the context of acting on those infrastructure SIP submissions.[5] Those commenters specifically raised concerns involving provisions in existing SIPs and with EPA's statements in other proposals that it would address two issues separately and not as part of actions on the infrastructure SIP submissions: (i) Existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction at sources, that may be contrary to the CAA and EPA's policies addressing such excess emissions (''SSM''); and (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that purport to permit revisions to SIP approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA (''director's discretion''). EPA notes that there are two other substantive issues for which EPA likewise stated in other proposals that it would address the issues separately: (i) Existing provisions for minor source new source review programs that may be inconsistent with

[1] The 8-hour averaging period replaced the previous 1-hour averaging period, and the level of the NAAQS was changed from 0.12 parts per million (ppm) to 0.08 ppm (62 FR 38856).

[2] The annual $PM_{2.5}$ standard was set at 15 micrograms per cubic meter (µg/m^3), based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors and the 24-hour $PM_{2.5}$ standard was set at 65 µg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area (62 FR 38652).

[3] The final rule revising the 24-hour NAAQS for $PM_{2.5}$ from 65 µg/m^3 to 35 µg/m^3 was published in the **Federal Register** on October 17, 2006 (71 FR 61144).

[4] In the September 2011 notice, EPA specifically found that Hawaii failed to submit for section 110(a)(2)(A)–(C), (D)(i)(II) (PSD prong only), (E)–(H) and (J)–(M). EPA had already determined on June 10, 2011 that Hawaii had failed to submit a complete SIP to address the attainment and maintenance requirements of section 110(a)(2)(D)(i)(I) (75 FR 32673).

[5] See, Comments of Midwest Environmental Defense Center, dated May 31, 2011. Docket # EPA–R05–OAR–2007–1179 (adverse comments on proposals for three states in Region 5).

the requirements of the CAA and EPA's regulations that pertain to such programs (''minor source NSR''); and (ii) existing provisions for Prevention of Significant Deterioration programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80,186 (December 31, 2002), as amended by 72 FR 32,526 (June 13, 2007) (''NSR Reform''). In light of the comments, EPA believes that its statements in various proposed actions on infrastructure SIPs with respect to these four individual issues should be explained in greater depth. It should be noted, however, that, unlike other States, Hawaii has submitted revisions to its minor NSR program as part of its Infrastructure SIP submittal. EPA is taking action on these revisions in a separate notice-and-comment rulemaking. Thus, the discussion below pertaining to ''existing provisions'' is not relevant to Hawaii's revised minor NSR rules.

EPA intended the statements in other proposals concerning these four issues merely to be informational, and to provide general notice of the potential existence of provisions within the existing SIPs of some States that might require future corrective action. EPA did not want States, regulated entities, or members of the public to be under the misconception that the Agency's approval of the infrastructure SIP submission of a given State should be interpreted as a reapproval of certain types of provisions that might exist buried in the larger existing SIP for such State. Thus, for example, EPA explicitly noted that the Agency believes that some states may have existing SIP-approved SSM provisions that are contrary to the CAA and EPA policy, but that ''in this rulemaking, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during SSM of operations at facilities.'' EPA further explained, for informational purposes, that ''EPA plans to address such State regulations in the future.'' EPA made similar statements, for similar reasons, with respect to the director's discretion, minor source NSR, and NSR Reform issues. EPA's objective was to make clear that approval of an infrastructure SIP for these NAAQS should not be construed as explicit or implicit reapproval of any existing provisions that relate to these four substantive issues.

Unfortunately, the commenters and others evidently interpreted these statements to mean that EPA considered action upon the SSM provisions and the other three substantive issues to be integral parts of acting on an infrastructure SIP submission, and therefore that EPA was merely postponing taking final action on the issues in the context of the infrastructure SIPs. This was not EPA's intention. To the contrary, EPA only meant to convey its awareness of the potential for certain types of deficiencies in existing SIPs, and to prevent any misunderstanding that it was reapproving any such existing provisions. EPA's intention was to convey its position that the statute does not require that infrastructure SIPs address these specific substantive issues in existing SIPs and that these issues may be dealt with separately, outside the context of acting on the infrastructure SIP submission of a state. To be clear, EPA did not mean to imply that it was not taking a full final agency action on the infrastructure SIP submission with respect to any substantive issue that EPA considers to be a required part of acting on such submissions under section 110(k) or under section 110(c). Given the confusion evidently resulting from EPA's statements in those other proposals, however, we want to explain more fully the Agency's reasons for concluding that these four potential substantive issues in existing SIPs may be addressed separately from actions on infrastructure SIP submissions.

Although section 110(a)(1) addresses the timing and general requirements for these infrastructure SIPs, and section 110(a)(2) provides more details concerning the required contents of these infrastructure SIPs, EPA believes that many of the specific statutory provisions are facially ambiguous. In particular, the list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive provisions, and some of which pertain to requirements for both authority and substantive provisions.[6] Some of the elements of section 110(a)(2) are relatively straightforward, but others clearly require interpretation by EPA through rulemaking, or recommendations through guidance, in order to give specific meaning for a particular NAAQS.[7]

Notwithstanding that section 110(a)(2) provides that ''each'' SIP submission must meet the list of requirements therein, EPA has long noted that this literal reading of the statute is internally inconsistent, insofar as section 110(a)(2)(I) pertains to nonattainment SIP requirements that could not be met on the schedule provided for these SIP submissions in section 110(a)(1).[8] This illustrates that EPA must determine which provisions of section 110(a)(2) may be applicable for a given infrastructure SIP submission. Likewise, EPA has previously decided that it could take action on different parts of the larger, general ''infrastructure SIP'' for a given NAAQS without concurrent action on all subsections.[9] Finally, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS and the attendant infrastructure SIP submission for that NAAQS. For example, the monitoring requirements that might be necessary for purposes of section 110(a)(2)(B) for one NAAQS could be very different than what might be necessary for a different pollutant. Thus, the content of an infrastructure SIP submission to meet this element from a state might be very different for an entirely new NAAQS, versus a minor revision to an existing NAAQS.[10]

[6] For example, section 110(a)(2)(E) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a substantive program to address certain sources as required by part C of the CAA; section 110(a)(2)(G) provides that states must have both legal authority to address emergencies and substantive contingency plans in the event of such an emergency.

[7] For example, section 110(a)(2)(D)(i) requires EPA to be sure that each state's SIP contains adequate provisions to prevent significant contribution to nonattainment of the NAAQS in other states. This provision contains numerous terms that require substantial rulemaking by EPA in order to determine such basic points as what constitutes significant contribution. See, e.g., ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule,'' 70 FR 25,162 (May 12, 2005) (defining, among other things, the phrase ''contribute significantly to nonattainment'').

[8] See, e.g., Id., 70 FR 25,162, at 63–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[9] For example, EPA issued separate guidance to states with respect to SIP submissions to meet section 110(a)(2)(D)(i) for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS. See, ''Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division OAQPS, to Regional Air Division Director, Regions I–X, dated August 15, 2006. In addition, EPA bifurcated the action on these ''interstate transport'' provisions within section 110(a)(2) and in most instances, substantive administrative actions occurred on different tracks with different schedules.

[10] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of

Continued

Similarly, EPA notes that other types of SIP submissions required under the statute also must meet the requirements of section 110(a)(2), and this also demonstrates the need to identify the applicable elements for other SIP submissions. For example, nonattainment SIPs required by part D likewise have to meet the relevant subsections of section 110(a)(2) such as section 110(a)(2)(A) or (E). By contrast, it is clear that nonattainment SIPs would not need to meet the portion of section 110(a)(2)(C) that pertains to part C, *i.e.,* the PSD requirements applicable in attainment areas. Nonattainment SIPs required by part D also would not need to address the requirements of section 110(a)(2)(G) with respect to emergency episodes, as such requirements would not be limited to nonattainment areas. As this example illustrates, each type of SIP submission may implicate some subsections of section 110(a)(2) and not others.

Given the potential for ambiguity of the statutory language of section 110(a)(1) and (2), EPA believes that it is appropriate for EPA to interpret that language in the context of acting on the infrastructure SIPs for a given NAAQS. Because of the inherent ambiguity of the list of requirements in section 110(a)(2), EPA has adopted an approach in which it reviews infrastructure SIPs against this list of elements ''as applicable.'' In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the purpose of the submission or the NAAQS in question, would meet each of the requirements, or meet each of them in the same way. EPA elected to use guidance to make recommendations for infrastructure SIPs for these ozone and $PM_{2.5}$ NAAQS.

On October 2, 2007, EPA issued guidance making recommendations for the infrastructure SIP submissions for both the 1997 8-hour ozone NAAQS and the 1997 $PM_{2.5}$ NAAQS.[11] Within this guidance document, EPA described the duty of states to make these submissions to meet what the Agency characterized as the ''infrastructure'' elements for SIPs, which it further described as the ''basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the standards.'' [12] As further identification of these basic structural SIP requirements, ''attachment A'' to the guidance document included a short description of the various elements of section 110(a)(2) and additional information about the types of issues that EPA considered germane in the context of such infrastructure SIPs. EPA emphasized that the description of the basic requirements listed on attachment A was not intended ''to constitute an interpretation of'' the requirements, and was merely a ''brief description of the required elements.'' [13] EPA also stated its belief that with one exception, these requirements were ''relatively self explanatory, and past experience with SIPs for other NAAQS should enable States to meet these requirements with assistance from EPA Regions.'' [14] For the one exception to that general assumption, however, *i.e.,* how States should proceed with respect to the requirements of section 110(a)(2)(G) for the 1997 $PM_{2.5}$ NAAQS, EPA gave much more specific recommendations. But for other infrastructure SIP submittals, and for certain elements of the submittals for the 1997 $PM_{2.5}$ NAAQS, EPA assumed that each State would work with its corresponding EPA regional office to refine the scope of a State's submittal based on an assessment of how the requirements of section 110(a)(2) should reasonably apply to the basic structure of the State's SIP for the NAAQS in question.

On September 25, 2009, EPA issued guidance to make recommendations to states with respect to the infrastructure SIPs for the 2006 $PM_{2.5}$ NAAQS.[15] In the 2009 Guidance, EPA addressed a number of additional issues that were not germane to the infrastructure SIPs for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS, but were germane to these SIP submissions for the 2006 $PM_{2.5}$ NAAQS. Significantly, neither the 2007 Guidance nor the 2009 Guidance explicitly referred to the SSM, director's discretion, minor source NSR, or NSR Reform issues as among specific substantive issues EPA expected states to address in the context of the infrastructure SIPs, nor did EPA give any more specific recommendations with respect to how States might address such issues even if they elected to do so. The SSM and director's discretion issues implicate section 110(a)(2)(A), and the minor source NSR and NSR Reform issues implicate section 110(a)(2)(C). In the 2007 Guidance and the 2009 Guidance, however, EPA did not indicate to States that it intended to interpret these provisions as requiring a substantive submission to address these specific issues in existing SIP provisions in the context of the infrastructure SIPs for these NAAQS. Instead, EPA's 2007 Guidance merely indicated its belief that the States should make submissions in which they established that they have the basic SIP structure necessary to implement, maintain, and enforce the NAAQS. EPA believes that States can establish that they have the basic SIP structure, notwithstanding that there may be potential deficiencies within the existing SIP.

EPA believes that this approach to the infrastructure SIP requirement is reasonable, because it would not be feasible to read section 110(a)(1) and (2) to require a comprehensive review of each and every provision of an existing SIP merely for purposes of assuring that the State in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts that, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA considers the overall effectiveness of the SIP. To the contrary, EPA believes that a better approach is for EPA to determine which specific SIP elements from section 110(a)(2) are applicable to an infrastructure SIP for a given NAAQS, and to focus attention on those elements that are most likely to need a specific SIP revision in light of the new or revised NAAQS. Thus, for example, EPA's 2007 Guidance specifically directed States to focus on the requirements of section 110(a)(2)(G) for the 1997 $PM_{2.5}$ NAAQS because of the absence of underlying EPA regulations for emergency episodes for this NAAQS and an anticipated absence of relevant provisions in existing SIPs.

new monitors to measure ambient levels of that new indicator species for the new NAAQS.

[11] See, ''Guidance on SIP Elements Required Under Section 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division, to Air Division Directors, Regions I–X, dated October 2, 2007 (the ''2007 Guidance'').

[12] Id. at page 2.

[13] Id. at attachment A, page 1.

[14] Id. at page 4. In retrospect, the concerns raised by commenters with respect to EPA's approach to some substantive issues indicate that the statute is not so ''self explanatory,'' and indeed is sufficiently ambiguous that EPA needs to interpret it in order to explain why these substantive issues do not need to be addressed in the context of infrastructure SIPs and may be addressed at other times and by other means.

[15] See, ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS),'' from William T, Harnett, Director Air Quality Policy Division, to Regional Air Division Directors, Regions I–X, dated September 25, 2009 (the ''2009 Guidance'').

Finally, EPA believes that its approach is a reasonable reading of section 110(a)(1) and (2) because the statute provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow the Agency to take appropriate tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or otherwise to comply with the CAA.[16] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[17] Significantly, EPA's determination that an action on the infrastructure SIP is not the appropriate time and place to address all potential existing SIP problems does not preclude the Agency's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on the infrastructure SIP, EPA believes that section 110(a)(2)(A) may be among the statutory bases that the Agency cites in the course of addressing the issue in a subsequent action.[18]

D. Proposed Interpretation of CAA Section 128

As noted above, EPA is currently acting upon infrastructure SIPs for various states across the country. Among the elements that EPA is evaluating as part of these actions is the requirement of CAA section 110(a)(2)(E)(ii) that SIPs, ''provide * * * requirements that the State comply with the requirements respecting State boards under section 128'' of the CAA. In contrast with, for example, the SSM issue discussed above, section 110(a)(2)(E)(ii) unambiguously mandates that each SIP must satisfy the requirements of section 128. Accordingly, as part of our infrastructure SIP actions, EPA is reviewing SIPs in relation to the requirements of CAA section 128. In this action, EPA finds it appropriate to propose certain interpretations of section 128 and invite comment on these interpretations.[19]

Congress added section 128 of the CAA in the 1977 amendments as the result of a conference agreement. Titled ''State boards,'' section 128 provides in relevant part:

> (a) Not later than the date one year after August 7, 1977, each applicable implementation plan shall contain requirements that—
>
> (1) Any board or body which approves permits or enforcement orders under [this Act] shall have at least a majority of members who represent the public interest and do not derive any significant portion of their income from persons subject to permits or enforcement orders under [this Act], and
>
> (2) Any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed.

In 1978, we issued a guidance memorandum recommending ways States could meet the requirements of section 128, including suggested interpretations of certain terms in section 128.[20]

We first note that, in the conference report, the committee stated: ''It is the responsibility of each State to determine the specific requirements to meet the general requirements of [section 128].'' [21] We think that this legislative history indicates that Congress intended states to have some latitude in the specifics of implementing section 128, so long as the implementation is consistent with the plain text of the section. We also note that Congress explicitly provided in section 128 that States could adopt more stringent requirements. As a result, we propose four important considerations for implementing section 128.

First, section 128 must be implemented through SIP-approved, federally enforceable provisions. Section 128 explicitly mandates that each SIP ''shall contain requirements'' that satisfy subsections 128(a)(1) and 128(a)(2). A mere narrative description of state statutes or rules, or of a state's current or past practice in constituting a board or body and in disclosing potential conflicts of interest, is not a requirement contained in the SIP and therefore does not satisfy the plain text of section 128.

Second, subsection 128(a)(1) applies only to states that have a board or body that is composed of multiple individuals and that, among its duties, approves permits or enforcement orders under the CAA. It does not apply in states that have no such multi-member board or body, and where instead a single head of an agency approves permits or enforcement orders under the CAA. This flows from the text of section 128 itself, for two reasons. First, as section 128(a)(1) refers to a majority of members in the plural, we think it reasonable to read section 128(a)(1) as not creating any requirements for an individual with sole authority for approving a permit or enforcement order under the CAA. Second, subsection 128(a)(2) explicitly applies to the head of an executive agency with ''similar powers'' to a board or body that approves permits or enforcement orders under the CAA, while subsection 128(a)(1) omits any reference to heads of executive agencies.[22] We infer that subsection 128(a)(1) should not apply to heads of executive agencies who approve permits or enforcement orders.

Third, subsection 128(a)(2) applies to all states, regardless of whether the state has a multi-member board or body that

[16] EPA has recently issued a SIP call to rectify a specific SIP deficiency related to the SSM issue. See, ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revision,'' 76 FR 21,639 (April 18, 2011).

[17] EPA has recently utilized this authority to correct errors in past actions on SIP submissions related to PSD programs. See, ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82,536 (December 30, 2010). EPA has previously used its authority under CAA 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, e.g., 61 FR 38,664 (July 25, 1996) and 62 FR 34,641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67,062 (November 16, 2004) (corrections to California SIP); and 74 FR 57,051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[18] EPA has recently disapproved a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, e.g., 75 FR 42,342 at 42,344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4,540 (January 26, 2011) (final disapproval of such provisions).

[19] If EPA finalizes this action, the proposed interpretations will supersede (to the extent that they are inconsistent with) interpretations suggested in the 1978 guidance, at least for Hawaii's SIP.

[20] Memorandum from David O. Bickart, Deputy General Counsel, to Regional Air Directors, Guidance to States for Meeting Conflict of Interest Requirements of Section 128 (Mar. 2, 1978).

[21] H.R. Rep. 95–564 (1977), reprinted in 3 *Legislative History of the Clean Air Act Amendments of 1977* 526–27 (1978).

[22] For the same two reasons, we distinguish the language of section 128(a)(1) from the language of the analogous provision in the Clean Water Act (CWA), governing composition of a state board or body that approves National Pollutant Discharge Elimination System (NPDES) permit applications. In relevant part, the CWA provision states, ''no board or body which approves permit applications or portions thereof shall include, as a member, any person who receives, or has during the previous two years received, a significant portion of his income directly or indirectly from permit holders or applicants for a permit.'' CWA section 304(i)(D), 33 U.S.C. 1314(i)(D). The CWA provision does not refer to a majority of members in the plural, and the CWA provision does not have a separate section explicitly including heads of executive agencies. Thus, the bases for our interpretation of subsection 128(a)(1) do not exist in the CWA.

approves permits or enforcement orders under the CAA. Although the title of section 128 is ''State boards,'' the language of section 128(a)(2) explicitly applies where the head of an executive agency, rather than a board or body, approves permits or enforcement orders. In instances where the head of an executive agency delegates his or her power to approve permits or enforcement orders, or where statutory authority to approve permits or enforcement orders is nominally vested in another state official, the requirement to disclose adequately potential conflicts of interest still applies. In other words, EPA thinks that SIPs for all states, regardless of whether a state board or body approves permits or enforcement orders under the CAA, must contain adequate provisions for disclosure of potential conflicts of interest. We note that many states have general disclosure provisions, applicable to all state employees, that may be adequate, if submitted for adoption into the SIP, to satisfy the requirements of subsection 128(a)(2).

Finally, a state may satisfy the requirements of section 128 by submitting for adoption into the SIP a provision of state law that closely tracks or mirrors the language of the applicable provisions of section 128. A state may do so in two ways. First, the state may adopt the language of subsections 128(a)(1) and 128(a)(2) verbatim. Under this approach, the state will be able to meet the continuing requirements of section 128 without any additional, future SIP revisions, even if the state adds or removes authority, either at the state level or local level, to individuals or to boards or bodies to approve permits or enforcement orders under the CAA. Second, the state may modify the language of subsections 128(a)(1) (if applicable) and 128(a)(2) to name the particular board, body, or individual official with approval authority. In this case, if the state subsequently modifies that authority, the state may have to submit a corresponding SIP revision to meet the continuing requirements of section 128. While either approach would meet the minimum requirements of section 128, we note that the statute explicitly permits states to adopt more stringent requirements, for example through providing more detailed definitions of the terms in subsections 128(a)(1) and 128(a)(2), such as those suggested in the 1978 guidance memorandum. This approach gives states flexibility in implementing section 128, while still ensuring consistency with the statute.

II. The State's Submittal and Related Actions by EPA

On December 14, 2011, the Hawaii Department of Health (HDOH) submitted revisions to the Hawaii SIP to address the infrastructure requirements of CAA section 110(a)(2) (''2011 Hawaii Infrastructure SIP''). This submittal included (1) provisions of the Hawaii Administrative Rules (HAR) to be included in the Hawaii SIP as regulatory materials; (2) provisions of the Hawaii Revised Statutes (HRS) to be included in the SIP as non-regulatory materials; and (3) an ''Infrastructure SIP Certification of Adequacy.'' The Certification sets forth HDOH's analysis of how the Hawaii SIP, with the submitted revisions, would satisfy the infrastructure SIP requirements of CAA section 110(a)(2) with respect to the 1997 ozone NAAQS and the 1997 and 2006 $PM_{2.5}$ NAAQS (collectively ''the relevant NAAQS'').[23] The 2011 Hawaii Infrastructure SIP also included supporting materials for each of the components of the SIP revision.

On February 1, 2012, EPA's Region 9 Regional Administrator signed a proposed rule and a direct final rule to approve into the Hawaii SIP a number of the regulatory provisions that were included in the 2011 Hawaii Infrastructure SIP. On March 20, 2012, the Regional Administrator signed a proposed rule and a direct final rule to approve into the SIP the remaining regulatory provisions submitted for inclusion in the SIP. These latter rules update and replace the minor NSR rules in the existing Hawaii SIP. Pre-publication versions of these rules and the accompanying TSDs have been placed in the docket for this action.

III. EPA's Evaluation and Proposed Action

EPA has evaluated the 2011 Hawaii Infrastructure SIP and the existing provisions of the Hawaii SIP in relation to the infrastructure SIP requirements for the relevant NAAQS. The Technical Support Document (TSD) for this action, which is available online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0228, includes a summary of our evaluation for each element.

Based upon this analysis, EPA proposes to approve the 2011 Hawaii Infrastructure SIP with respect to the following requirements:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C) (in part): Program for enforcement of control measures and regulation of new stationary sources (minor NSR program only).
- Section 110(a)(2)(D)(i)(I): Interstate transport (significant contribution and interference with maintenance).
- Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
- Section 110(a)(2)(F): Stationary source monitoring and reporting.
- Section 110(a)(2)(G): Emergency episodes.
- Section 110(a)(2)(H): SIP revisions.
- Section 110(a)(2)(J) (in part): Public notification.
- Section 110(a)(2)(K): Air quality modeling and submission of modeling data.
- Section 110(a)(2)(L): Permitting fees.
- Section 110(a)(2)(M): Consultation/participation by affected local entities.

In addition, we are proposing to approve into the SIP as non-regulatory materials the statutory provisions that HDOH included as part of the 2011 Hawaii Infrastructure SIP.[24]

We are proposing to disapprove the 2011 Hawaii Infrastructure SIP with respect to the following infrastructure SIP requirements:

- Section 110(a)(2)(C) (in part): Program for enforcement of control measures and regulation of new stationary sources (permit program as required in part C of title I of the Act).
- Section 110(a)(2)(D)(i)(II): Interstate transport—prevention of significant deterioration and visibility protection.
- Section 110(a)(2)(D)(ii): Interstate pollution abatement and international air pollution.
- Section 110(a)(2)(J) (in part): Consultation with government officials and PSD.

As explained in the TSD, our proposed disapproval of these elements and sub-elements is compelled by the absence of an approvable SIP revision from Hawaii that meets the PSD requirements of sections 160 through 165 of the CAA.[25] In addition, our proposed disapproval of Section 110(a)(2)(D)(i)(II) is compelled

[23] A copy of the complete 2011 Hawaii Infrastructure SIP submittal has been placed in the docket for this action and is available online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0228.

[24] A list of these statutory provisions and their complete text are found in Attachment 1 and Appendix A of the 2011 Hawaii Infrastructure SIP, respectively. These documents have been placed in the docket for this action and are available online at *http://www.regulations.gov,* docket number EPA–R09–OAR–2012–0228.

[25] See 40 CFR 52.632.

by the lack of approvable SIP revisions to address reasonably attributable visibility impairment (RAVI) and regional haze affecting mandatory Class I areas.[26] Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of part D, title I of the CAA (CAA sections 171–193) or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP Call) starts a sanctions clock. The 2011 Hawaii Infrastructure SIP was not submitted to meet either of these requirements. Therefore, any action we take to finalize the described disapproval will not trigger sanctions.

In addition, these deficiencies have previously been addressed through promulgation of a PSD FIP (43 FR 26410, June 19, 1978, as amended at 45 FR 52741, Aug. 7, 1980; 68 FR 11322, Mar. 10, 2003; 68 FR 74488, Dec. 24, 2003) and a FIP addressing RAVI (50 FR 28553, July 12, 1985, as amended at 52 FR 45137, Nov. 24, 1987). The requirement to address regional haze will be addressed through final action on a regional haze SIP and/or FIP for Hawaii, which must be signed by September 15, 2012, under the terms of a proposed consent decree.[27] Therefore, this disapproval, if finalized, would not trigger any new FIP obligations.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations (42 U.S.C. 7410(k), 40 CFR 52.02(a)). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves some state law as meeting Federal requirements and disapproves other state law because it does not meet Federal requirements; this proposed action does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999); is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Oxides of nitrogen, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 27, 2012.

Keith Takata,

Acting Regional Administrator, Region IX.

[FR Doc. 2012–8848 Filed 4–11–12; 8:45 am]

BILLING CODE 6560–50–P

[26] See 40 CFR 52.633 (reasonably attributable visibility impairment) and 74 FR 2392 (Jan. 15, 2009) (regional haze).

[27] We have placed a copy of the proposed consent decree in the docket for this action.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1983–0002; FRL–9657–6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the A & F Material Reclaiming, Inc. Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is issuing a Notice of Intent to Delete the A & F Material Reclaiming, Inc. Superfund Site (Site) located in Greenup, Illinois from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Illinois, through the Illinois Environmental Protection Agency (IEPA), have determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by May 14, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1983–0002, by one of the following methods:

- *http://www.regulations.gov:* Follow online instructions for submitting comments.
- *Email:* Gladys Beard, NPL Deletion Process Manager, at *beard.gladys@epa.gov* or Janet Pope, Community Involvement Coordinator, at *pope.janet@epa.gov.*
- *Fax:* Gladys Beard, NPL Deletion Process Manager, at (312) 697–2077.
- *Mail:* Gladys Beard, NPL Deletion Process Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–7253; or Janet Pope, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 353–0628 or (800) 621–8431.
- *Hand delivery:* Janet Pope, Community Involvement Coordinator, U.S. Environmental Protection Agency

(SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–1983–0002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket

All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at:

- U.S. Environmental Protection Agency—Region 5, 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 353–1063, Hours: Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding federal holidays.
- Greenup City Clerk's Office, Greenup Municipal Building, 115 Cumberland Avenue, Greenup, IL 62424, Phone: (217) 923–3401, Hours: Monday through Friday, 7:30 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Gladys Beard, NPL Deletion Process Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–7253, or *beard.gladys@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing a direct final Notice of Deletion of the A & F Material Reclaiming Inc. Superfund Site without prior Notice of Intent to Delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the ''Rules and Regulations'' section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, and Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Dated: March 19, 2012.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2012–8859 Filed 4–11–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2012–0003; 4500030113]

Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the Eastern or Southern Rocky Mountain Population of the Boreal Toad as an Endangered or Threatened Distinct Population Segment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of petition finding and initiation of status review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 90-day finding on a petition to list either the Eastern population or the Southern Rocky Mountain (SRM) population of the boreal toad (*Anaxyrus boreas boreas*) as a distinct population segment (DPS) that is endangered or threatened under the Endangered Species Act of 1973, as amended (Act), and to designate critical habitat. Based on our review, we find that the petition presents substantial scientific or commercial information indicating that listing the Eastern population of the boreal toad as a DPS may be warranted. We did not find substantial information that listing the SRM population of the boreal toad as a DPS may be warranted. Therefore, with the publication of this notice, we are initiating a review of the status of the Eastern population to determine if listing it as a DPS is warranted. To ensure that this status review is comprehensive, we are requesting scientific and commercial data and other information regarding the potential DPS. Based on the status review, we will issue a 12-month finding on the petition, which will address whether the petitioned action is warranted, as provided in the Act.

DATES: To allow us adequate time to conduct this review, we request that we receive information on or before June 11, 2012. The deadline for submitting an electronic comment using the Federal eRulemaking Portal (see **ADDRESSES** section, below) is 11:59 p.m. Eastern Time on this date. After June 11, 2012, you must submit information directly to the Field Office (see **FOR FURTHER INFORMATION CONTACT** section below). Please note that we might not be able to address or incorporate information that we receive after the above requested date.

ADDRESSES: You may submit information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Enter Keyword or ID box, enter Docket No. FWS–R6–ES–2012–0003, which is the docket number for this action. Then click on the Search button. You may submit a comment by clicking on ''Send a Comment or Submission.''

(2) *By hard copy:* Submit by U.S. mail or hand–delivery to: Public Comments Processing, Attn: FWS–R6–ES–2012–0003; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all information we receive on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Request for Information section below for more details).

FOR FURTHER INFORMATION CONTACT: Western Colorado Supervisor, Western Colorado Ecological Services Office, Grand Junction, CO; by telephone at 970–243–2778; or by facsimile at 970–245–6933. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Request for Information

When we make a finding that a petition presents substantial information indicating that listing a species may be warranted, we are required to promptly review the status of the species (status review). For the status review to be complete and based on the best available scientific and commercial information, we request information on the Eastern population of the boreal toad from governmental agencies, Native American tribes, the scientific community, industry, and any other interested parties. We seek information on:

(1) The species' biology, range, and population trends, including:

(a) Habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat or both.

(2) The factors that are the basis for making a listing determination for a species under section 4(a) of the Act (16 U.S.C. 1531 *et seq.*), which are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

If, after the status review, we determine that listing the Eastern population of the boreal toad is warranted, we will propose critical habitat (see definition in section 3(5)(A) of the Act) under section 4 of the Act, to the maximum extent prudent and determinable at the time we propose to list the species. Therefore, we also request data and information on:

(1) What may constitute ''physical or biological features essential to the conservation of the species,'' within the geographical range currently occupied by the species;

(2) Where these features are currently found;

(3) Whether any of these features may require special management considerations or protection;

(4) Specific areas outside the geographical area occupied by the species that are ''essential for the conservation of the species''; and

(5) What, if any, critical habitat you think we should propose for designation if the species is proposed for listing, and why such habitat meets the requirements of section 4 of the Act.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your information concerning this status review by one of the methods listed in the **ADDRESSES** section. If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Information and supporting documentation that we received and used in preparing this finding is available for you to review at *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Western Colorado Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

Section 4(b)(3)(A) of the Act requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are to base this finding on information provided in the petition, supporting information submitted with the petition, and information otherwise available in our files. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition and publish our notice of the finding promptly in the **Federal Register**.

Our standard for substantial scientific or commercial information within the Code of Federal Regulations (CFR) with regard to a 90-day petition finding is ''that amount of information that would lead a reasonable person to believe that the measure proposed in the petition may be warranted'' (50 CFR 424.14(b)). If we find that substantial scientific or commercial information was presented, we are required to promptly conduct a species status review, which we subsequently summarize in our 12-month finding.

Petition History

On May 25, 2011, we received a petition of the same date from the Center for Biological Diversity, the Center for Native Ecosystems, and the Biodiversity Conservation Alliance, requesting that either the Eastern or SRM population of the boreal toad be listed as an endangered or threatened DPS and that critical habitat be designated under the Act. The petitioners also requested that if boreal toads in either the Eastern or SRM population are designated as separate species during consideration of the petition (based on recent and ongoing genetic studies) that both species be listed under the Act. We note the request to list either population as a DPS, or, if the two populations are found to be separate species, to list each as a separate species; however, there are currently no scientific papers calling for species designations for these two populations. Consequently, this 90-day finding examines only the possibility of listing the Eastern or SRM population as a DPS or two DPSs, and not the species question.

The petitioners included the requisite information in the petition, as required at 50 CFR 424.14(a). In a June 23, 2011, letter to the petitioners, we responded that we reviewed the information presented in the petition and determined that issuing an emergency regulation temporarily listing the species as endangered under section 4(b)(7) of the Act was not warranted. We also stated that we would initiate response to the petition in Fiscal Year 2011 and would finalize a response in Fiscal Year 2012 (approximately March 2012). This finding addresses the petition.

Previous Federal Action(s)

On September 30, 1993, the Service received a petition from the Biodiversity Legal Foundation of Boulder, Colorado, and Dr. Peter Hovingh, a researcher at the University of Utah, Salt Lake City, Utah. The petitioners requested that the Service list the SRM population of the ''western boreal toad'' (a common name sometimes used in the past for *Anaxyrus boreas boreas*) as endangered throughout its range in northern New Mexico, Colorado, and southeastern Wyoming. The petitioners also requested that the Service designate critical habitat. We published a notice of a 90-day finding for the petition in the **Federal Register** on July 22, 1994 (59 FR 37439), indicating that the petition and other readily available scientific and commercial information presented substantial information that the petitioned action may be warranted.

On March 23, 1995, the Service announced a 12-month finding that listing the SRM population of the boreal toad as an endangered DPS was warranted but precluded by other higher priority actions (60 FR 15281). At that time, a listing priority number of 3 was assigned. When we find that a species is warranted but precluded for listing, we refer to it as a candidate species. Section 4(b)(3)(B) of the Act directs that when we make a ''warranted but precluded'' finding on a petition, we are to treat the petition as being one that is resubmitted annually on the date of the finding; thus, the Act requires us to reassess the petitioned actions and to publish a finding on the resubmitted petition on an annual basis. Several resubmitted candidate assessments for the boreal toad were completed. The most recent assessment was published in the **Federal Register** on May 11, 2005 (70 FR 24870).

On October 7, 2002, as part of an agreement regarding multiple species, the U.S. Department of the Interior reached an out-of-court settlement with several conservation organizations and agreed to make a final determination for listing the SRM population of the boreal toad by no later than September 30, 2005. In the 2005 Annual Notice of Findings on Resubmitted Petitions, we noted that a determination for the boreal toad would be funded in Fiscal Year 2005 (70 FR 24870). On September 29, 2005, we reached a determination in the revised 12-month Finding that the SRM population of the boreal toad did not warrant listing because it was not a listable entity according to the DPS criteria and, therefore, should be withdrawn from the candidate list (70 FR 56880). When the boreal toad was put on the candidate list in 1995, the DPS policy did not yet exist, so current criteria were not used to determine whether the toad was a listable entity. The combination of using the DPS criteria developed in1996 and genetic and other information available during development of the 2005 finding led to determinations that the SRM population of the boreal toad was discrete based on DPS discreteness criteria but was not significant based on DPS significance criteria. Therefore, it was not considered a listable entity.

On September 2, 2008, we received a notice of intent to sue from the Center for Biological Diversity (dated August 28, 2008) for violations of the Act (i.e., failure to issue a proposed rule in 2005 or subsequently list the toad), but a lawsuit never followed.

Species Information

Taxonomy

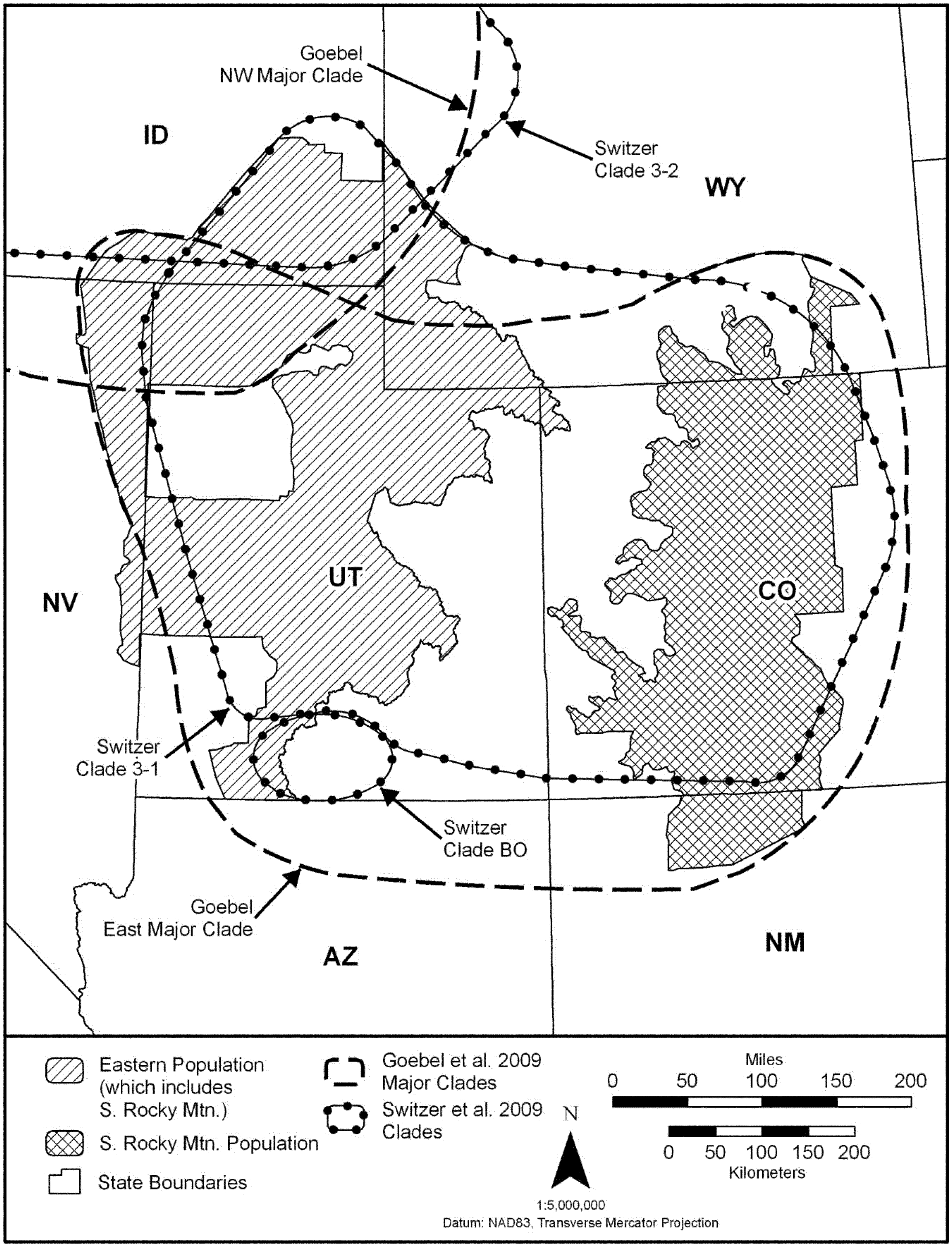
The *Anaxyrus boreas* (formerly *Bufo boreas*) group of toads, of which the boreal toad is a subspecies, are amphibians that occur throughout much of the western United States. The species was first described from specimens collected on the Columbia River (Washington or Oregon) and Puget Sound (Washington) by Baird and Girard (1852). The genus for the boreal toad was revised from *Bufo* to *Anaxyrus* in 2006 (Frost *et al.* 2006, pp. 10, 213, 218, 222, 281, 329, 350, 363), and the Service accepts this revision.

Two subspecies of the boreal toad have been recognized for many years, the boreal toad (*A. b. boreas,* the subject of this finding) and the California toad (*A. b. halophilus*) (Camp 1917, p. 116). Other authors recognize up to four subspecies, with the Amargosa toad (*A. nelsoni* or *A. b. nelsoni*) and black toad (*A. exsul*) or (*A. b. exsul*) being the other two potential subspecies (Crother 2000 (2001), p. 7; 2008, pp. 2–4; Stebbins 2003, pp. 208–209, map 32). The Yosemite toad (*A. canorus*) also is considered to be a distinct but closely related species (Stebbins 2003, p. 210–211). All of the toad species and subspecies mentioned above are considered by Goebel *et al.* (2009, pp. 221, 223) and Switzer *et al.* (2009, pp. 25–26) to comprise the *A. boreas* group. Deoxyribonucleic acid (DNA) analyses by these two sets of authors suggest that a taxonomic change to the *A. boreas* group could be appropriate.

Two different studies analyzing mitochondrial DNA (mtDNA) from boreal toads and other closely related species and subspecies conclude that toads within the SRM population (southeastern Wyoming, Colorado, and New Mexico) and southwestern Wyoming, southeastern Idaho, northeastern Nevada, and Utah form a population of genetically similar toads termed the Eastern Major Clade (Goebel *et al.* 2009, p. 210, fig. 1) or Clade 3–1 (Switzer *et al.* 2009, p. 8). The combination of these two clades (populations of genetically similar toads), the Eastern Major Clade and Clade 3–1, primarily form the Eastern population (see the map in this notice). Switzer *et al.* (2009, fig. 3) also identify a smaller clade (named Clade BO by Switzer *et al.*) based on a distinct haplotype in southern Utah that constitutes a small part of the Eastern population (see the map in this **Federal Register** notice). Also examined within this finding are boreal toads found within the part of the Northwest Major Clade that overlaps with the Eastern Major Clade (Goebel 2003, p. 2; Goebel *et al.* 2009, p. 210, fig. 1). This overlap is further supported by Switzer *et al.* (2009, fig. 3), who found that the area they designated as Clade 3–2 overlaps with Clade 3–1 (see the map in this notice). Clade 3–2 is a weakly supported clade that, in combination with Clade 3–3 and sister Clade 3–4, constitutes the larger Clade 4–1 discussed in Switzer *et al.* (2009, pp. 9–10, fig. 2).

The Northwest Major Clade extends from western Wyoming and northwestern Utah over to west-central California and up to southeastern Alaska, including ranges of both the boreal toad and the California toad (Goebel *et al.* 2009, p. 215). The Eastern Major Clade extends from central Colorado to northeastern Nevada, and from southern Wyoming to northern New Mexico and Arizona (see the map in this notice). All of the toads within the Eastern Major Clade and overlap area of the Northwest Major Clade (or Clades 3–1 and 3–2) are considered to be boreal toads (Goebel *et al.* 2009, p. 215; Switzer *et al.* 2009, p. 3) (see the map in this notice).

BILLING CODE 4310–55–P



Map. The Eastern population and southern Rocky Mountain subset of the Eastern population.

BILLING CODE 4310–55–C

As illustrated in the map in this notice, the combination of the outermost extent of both 2009 genetic articles' clade boundaries primarily form the boundaries of the Eastern population. Two exceptions occur in west-central Utah and eastern Nevada, where the Eastern population boundary extends beyond the clade boundaries (see map). The petitioners based the Eastern population boundaries on gross range maps drawn by the International Union for Conservation of Nature, creating the two exceptions. Reduction in size of the Eastern population from clade boundaries also occurs in Arizona, northwestern New Mexico, and the other States, based on lack of habitat and no records of boreal toads ever occurring in the excluded areas (see map).

Portions of Goebel *et al.*'s (2009, p. 210, fig. 1) Northwest Major Clade and Switzer *et al.*'s (2009, fig. 3) Clade 3–2 are illustrated in the map in this notice, and discussed in the ''Evaluation of Listable Entities'' section below, because of their geographic and genetic overlap with the Eastern Major Clade and Clade 3–1 and their necessary consideration in making a determination on whether the Eastern population is a listable entity. The other petitioned entity, the SRM population of the boreal toad, is a subset of the Eastern population (see map).

Biology

Boreal toads may reach a length (snout to vent) of 12.7 centimeters (5 inches) (Hammerson 1999, p. 90; Stebbins 2003, p. 208). They possess warty skin, oval parotoid glands, and often have a distinctive light mid-dorsal stripe. During the breeding season, males develop a dark patch on the inner surface of the innermost digit. Unlike many other toad species, the boreal toad has no vocal sac and, therefore, produces no mating call (Hammerson 1999, p. 90). Tadpoles are black or dark brown.

Boreal toads in the SRM population typically occupy habitat at elevations between 2,440 meters (m) (8,000 feet (ft)) and 3,350 m (11,000 ft) (Loeffler 2001, p. 6). However, within the Eastern population, they have been recorded as low as 1,570 m (5,150 ft) and as high as 3,661 m (12,000 ft) (Livo and Yeakley 1997, p. 143; Thompson *et al.* 2004, p. 256; Hogrefe *et al.* 2005, p. 7). Boreal toads occurring further north and west from the SRM population occupy lower elevations and are found down to sea level on the Pacific coast (Stebbins 2003, p. 209). At higher elevations, adult boreal toads emerge from winter refugia when snowmelt has cleared an opening from their burrows and daily temperatures remain above freezing (Campbell 1970a, pp. 22, 99; Campbell 1970b, p. 281). Breeding can occur from late January to July, depending on latitude, elevation, and local conditions (Stebbins 2003, p. 209). Breeding occurs during a 2- to 4-week period from mid-May to mid-June at lower elevations, and as late as mid-July at higher elevations in the SRM population (Hammerson 1999, p. 96). Suitable breeding sites are large bodies of water or small pools, beaver ponds, glacial kettle ponds, roadside ditches, human-made ponds, and slow-moving streams (Campbell 1970a, pp. 24–25; Hammerson 1999, p. 95).

Boreal toads have been observed to lay up to 16,500 eggs (Campbell 1970a, p. 24), and, in Colorado they have been observed laying up to 10,900 eggs (Hammerson 1999, p. 96), with an overall mean clutch size of 6,661 eggs (Carey *et al.* 2005, p. 224). The eggs are black and are deposited in long double-layer jelly strings, with one to three rows of eggs (Hammerson 1999, p. 90). Eggs hatch 1 to 2 weeks after being laid. Egg and tadpole development is temperature-dependent, and reproductive efforts may fail if tadpoles do not have sufficient time to metamorphose before the onset of winter. Persistent, shallow bodies of water are critical to breeding success, and if the breeding site dries before metamorphosis is complete, desiccation of the tadpoles or eggs will occur. Tadpoles typically metamorphose by late July to late August, but at higher elevations metamorphosis may not be complete until late September (Loeffler 2001, p. 7). Recently metamorphosed toadlets (metamorphs) aggregate within a few meters of the water and move into nearby moist habitats later in summer.

After mating, adults often disperse to upland, terrestrial habitats, where they are mostly active during the day in early and late summer (Mullally 1958, entire; Campbell 1970a, pp. 84–86; Carey 1978, pp. 203, 206, 211), foraging primarily on ants, beetles, spiders, and other invertebrates (Schonberger 1945, p. 121; Campbell 1970a, p. 69–71). Late in the summer the toads will expand their home ranges, generally in the direction of wintering habitats, which include cavities among streamside boulders, ground squirrel burrows, and beaver lodges and dams (Campbell 1970a, pp. 50, 87; Hammerson 1999, p. 94).

Survival of embryos from laying to hatching is normally high, but catastrophic mortality has been observed (Blaustein and Olson 1991, entire). Survival of tadpoles and juveniles is low, with predation and adverse environmental conditions primarily responsible for mortality at these life stages (Campbell 1970a, p. 61). Between 95 and 99 percent of juveniles die before reaching their second year of life (Samollow 1980, p. 33). The minimum age of breeding boreal toads is about 4 years in males and 6 years in females (Hammerson 1999, p. 97). Females may skip 1 to 3 years between breeding attempts, and individuals may live approximately 11 or 12 years (Olson 1991, pp. 7, 14).

Distribution, Abundance, and Trends

The range of the boreal toad subspecies (*Anaxyrus boreas boreas*) extends from coastal Alaska south and east through the Yukon Territory, the extreme southwest corner of the Northwest Territory, British Columbia, western Alberta, Washington, Oregon, northern California, northern Nevada, Idaho, western Montana, western and southeastern Wyoming, central and northern Utah, central to western Colorado, and extreme north-central New Mexico (Stebbins 2003, map 32; Goebel *et al.* 2009, p 210). No records of the boreal toad exist from Arizona or northwestern New Mexico, and, therefore, we do not consider the range of the boreal toad to include Arizona or northwestern New Mexico.

The range of the SRM population includes southeastern Wyoming through the mountainous region of central to west-central Colorado, and into extreme north-central New Mexico. The range of the Eastern population encompasses the SRM population and also includes southwestern Wyoming, southeastern Idaho, northeastern Nevada, and Utah (Goebel *et al.* 2009, p. 210; Switzer *et al.* 2009, p. 8, figure 3; Greenwald *et al.* 2011, pp. 17, 56–72) (see the map in this notice).

SRM Population

Southeastern Wyoming

In southeastern Wyoming, the boreal toad was once widespread and numerous in the Medicine Bow, Pole, Snowy, and Sierra Madre Mountain Ranges (Baxter and Stone 1985, p. 31; Keinath and Bennett 2000, p. 4). Declines in populations were documented in southeastern Wyoming from 1986 through 1988 (Corn *et al.* 1989, pp. iv, 26), and the subspecies is now rare in southeastern Wyoming (Keinath and Bennett 2000, p. 4; Jackson 2008, p. 4). Distribution, abundance, and trends of SRM toads are based on field monitoring from 1997 through 2011, but the latest written report ends with the 2007 field season (Jackson

2008, entire). In 2003, toads were observed in only seven southeastern Wyoming locations (in Albany and Carbon Counties). Only one breeding population is known to occur in southeastern Wyoming (Jackson 2008, pp. 91–92; Colorado Division of Wildlife 2010, p. 1). However, this population does not meet the population viability criteria established in the SRM conservation plan that was written by the State-led Boreal Toad Recovery Team (composition of Team described in Factor D) (Loeffler 2001, p. 17–18). The viability criteria specify the number of adults required at a breeding site, the frequency of breeding activity, and the amount of egg production and recruitment needed to maintain a viable population. The criteria also specify that a viable population must face no known significant and imminent threats to its habitat, health, or environmental conditions.

Colorado

In Colorado, the boreal toad was historically known to occur in 25 counties, and was common throughout the higher elevations (Burger and Bragg 1947, pp. 61–62; Smith *et al.* 1965, p. 5; Keinath and McGee 2005, p. 22), except for the Sangre de Cristo Mountains, Wet Mountains, and Pikes Peak region (Hammerson 1999, p. 90). Disappearances of 11 populations in the West Elk Mountains were documented between 1974 and 1982 (Carey 1993, pp. 357–358). Surveys of 59 historically occupied localities in Colorado between 1986 and 1988 failed to find individuals in 83 percent (49 locations) of the sites (Corn *et al.* 1989, p. iv). Surveys conducted in 1989 (249 locations) and 1991 (377 locations) in suitable habitat and historical locations resulted in finding boreal toads at 2 and 1 location, respectively (Hammerson 1989, pp. 41, 46, 50, 52, 53; Hammerson 1992, pp. 2, 142). The number of known breeding populations increased from 1996 to 2007, from the high teens to mid-40s; however, the number of individuals in some breeding populations have declined significantly from large numbers in the late 1990s or early 2000s to relatively few individuals as of 2007. Many more breeding sites and breeding populations have had very few toads observed since their initial discovery (Jackson 2008, pp. 12–91, 94). Despite knowledge of increased numbers of locations of boreal toads, the Boreal Toad Recovery Team identified only one population meeting the SRM conservation plan definition of viable in 2006 and 2007, versus a high of six populations in 1999 (Loeffler 2001, p. 17–18; Jackson 2008, p. 11). The lower number of viable populations is primarily due to detection of chytrid fungus (*Batrachochytrium dendrobatidis*), hereafter abbreviated ''Bd,'' a threat suspected in decline of boreal toad numbers and distribution (Jackson 2008, pp. 6, 10). The above information suggests boreal toad populations are declining in Colorado.

New Mexico

The boreal toad was known to occur in three Rio Arriba County, New Mexico, localities: Lagunitas, Canjilon, and Trout Lakes (Campbell and Degenhardt 1971, entire; Jones 1978, p. 3; New Mexico Department of Game and Fish (NMDGF) 1988, p. 1; Degenhardt *et al.* 1996, p. 49). Declines were first documented in New Mexico in the mid-1980s (Woodward and Mitchell 1985, p. 5; Carey 1987, pp. 1, 3). Surveys in 1993 revealed no populations at the three previously known locations (Stuart and Painter 1994, p. 115). No boreal toads were observed during surveys of the Trout Lakes and Lagunitas areas of New Mexico in 2004 (Jackson 2005, p. 41). Consequently, in 2008 a repatriation program was started at Trout Lakes with over 4,000 Colorado-reared tadpoles being released (NMDGF 2008, p. 2; USFWS 2009, p. 3). In 2009, over 3,400 tadpoles were released at Trout Lakes (NMDGF 2010, p. 4–5; USFWS 2010, p. 3). In 2009, only seven boreal toads from the 2008 release were recaptured (NMDGF 2010, p. 3).

In summary, based on currently available data, the distribution and abundance of boreal toads in the SRM population appears to be declining.

Eastern Population, Excluding the SRM Portion of the Population (see above)

Southwestern Wyoming

Relatively recent records (1993–2003) and historical records (pre-1993) of boreal toad locations were compiled for southwestern Wyoming (McGee and Keinath 2004, pp. 65–66). Historically, boreal toads occurred in Uinta and Lincoln Counties in the southwestern corner and west-central edge of Wyoming. One (nonbreeding) record from far eastern Lincoln County was recorded in the 1993–2003 time period. Other recent records in the region are from Sublette County bordering the eastern side of Lincoln County. Juvenile or recently metamorphosed toads and tadpoles were collected in Sublette County, Wyoming, for genetic analysis. The most southerly of the three toad samples was grouped with the Eastern population by Goebel (2003, p. 7). We do not have more recent distribution or status information in our files for southwestern Wyoming.

Southeastern Idaho

Two genetic sample sites in southeastern Idaho occur within the Eastern population (Switzer *et al.* 2009, fig. 3 and table 8). We do not currently have additional information on boreal toad distribution or status in southeastern Idaho.

Northeastern Nevada

One boreal toad genetic sample has been collected in northeastern Nevada (Goebel *et al.* 2009, pp. 210 and 212). We currently have no additional information on the distribution or status of boreal toads in northeastern Nevada.

Utah

The petition states that boreal toads are largely distributed throughout most of their historical range in Utah, which includes northern and central Utah (referencing Thompson *et al.* 2004, entire). Toads were considered to be irregularly distributed, and not all historical areas were occupied at the time of the Utah Boreal Toad Conservation Plan's development (Hogrefe *et al.* 2005, p. 5). The Utah Conservation Plan states that between 1995 and 2004, toads were recorded at a minimum of 102 localities (Hogrefe *et al.* 2005, p. 5), and eight populations were considered viable (Hogrefe *et al.* 2005, p. 1). Ten populations in 2009 were considered viable according to the definition in the Utah Conservation Plan (Utah Division of Wildlife Resources (UDWR) 2010, pp. I–16, I–17, II–10, III–5, IV–12).

In summary, based on currently available data, the number of viable populations appears stable in Utah, but little information exists to evaluate the current distribution or trend in abundance in the Eastern population outside of the boundaries of the SRM population.

Evaluation of Listable Entities

Under section 3(16) of the Act, we may consider for listing any species, including subspecies, of fish, wildlife, or plants, or any DPS of vertebrate fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). Such entities are considered eligible for listing under the Act (and, therefore, are referred to as listable entities) if we determine that they meet the definition of an endangered or threatened species. The petitioners have requested that either the SRM population of the boreal toad or the Eastern population of the boreal toad be considered a DPS and listed as endangered or threatened under the Act.

Distinct Vertebrate Population Segment

In determining whether an entity constitutes a DPS, and is therefore listable under the Act, we follow the Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (DPS Policy) (61 FR 4722; February 7, 1996). Under our DPS Policy, we analyze three elements prior to listing a possible DPS: (1) The discreteness of the population segment in relation to the remainder of the taxon; (2) the significance of the population segment to the taxon to which it belongs; and (3) the population segment's conservation status in relation to the Act's standards for listing (e.g., is the population segment, when treated as if it were a species, endangered or threatened?) (61 FR 4722). This finding considers whether the petitioned SRM population or Eastern population of the boreal toad may be a DPS.

Discreteness

Under our DPS Policy, a population segment of a vertebrate species may be considered discrete if it satisfies either one of the following conditions: (1) It is markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence of this separation); or (2) it is delimited by international governmental boundaries within which significant differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist (61 FR 4722).

Significance

Under our DPS Policy, in addition to our consideration that a population segment is discrete, we consider its biological and ecological significance to the taxon to which it belongs. This consideration may include, but is not limited to, the following:

(1) Evidence of the persistence of the discrete population segment in an ecological setting that is unusual or unique for the taxon;

(2) Evidence that loss of the discrete population segment would result in a significant gap in the range of a taxon;

(3) Evidence that the discrete population segment represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere as an introduced population outside its historical range; or

(4) Evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics (61 FR 4722).

Discreteness Information Provided in the Petition

The petition cites two genetic studies (Goebel *et al.* 2009, entire; Switzer *et al.* 2009, entire) that the petitioners believe support either that (1) the Eastern population, which would include the SRM population, is markedly separate from other boreal toad populations because of genetic differences and geographic separation, or (2) the SRM population is markedly separate from the rest of the Eastern population, as well as all other boreal toad populations, due to geographic separation. The petitioners recognize there may be overlap in genetics and geography between the Eastern and SRM populations, as well as with other populations within the range of the species, but they believe that the level of overlap is within the bounds allowed by the DPS policy in that the DPS policy does not ''require absolute reproductive isolation as a prerequisite to recognizing a distinct population segment'' (61 FR 4722).

Significance Information Provided in the Petition

The petition states that both the Eastern population and SRM population occur in an unusual or unique ecological setting. The petition also states that a significant gap in the range could occur if boreal toads are extirpated from either the Eastern population (a 20 percent (or 161,422 square miles) loss of the species' range in the conterminous United States) or SRM population (a 5 percent (or 38,894 square miles) loss of the species' range in the conterminous United States). Furthermore, the petition states that the Eastern population is significant based on Goebel *et al.* (2009, entire) and Switzer *et al.* (2009, entire). The petition further states that evidence shows that the SRM population may be significant based on the potential for the SRM population to be its own evolutionary unit as evidenced by geographic separation and greater diversity than currently recognized species (Goebel *et al.* 2009, pp. 213, 221).

Evaluation of Information Provided in the Petition and Available in Service Files on Discreteness of the SRM Population

Based on evidence of feasible dispersal distances, the SRM population is likely geographically (physically) separated from other populations of the boreal toad, including the western portion of the Eastern population (Keinath and McGee 2005, p. 16, fig. 7 and pp. 26–27) (see the map in this notice). The greatest recorded distance of movement for a boreal toad in the southern Rocky Mountains is 8 kilometers (km) (5 miles (mi)) (Lambert 2003, p. 88). The map in this notice illustrates the gross range of the western part of the Eastern population and the SRM population. We used complete hydrologic units to develop the eastern boundary of the western part of the Eastern population. The petition maps did not use complete hydrologic units, particularly in northeastern Utah, but rather cut them off at State boundaries. The Red Desert separates these two portions of the Eastern population in Wyoming by about 126 km (78 mi), and arid habitat in western Colorado and eastern Utah create separation of at least 84 km (52 mi). However, boreal toads are not known to actually occupy the outer extent (lower elevations) of the gross hydrologic units in the map in this notice. Maps in the petition can be referred to in order to see hydrologic units known to be occupied by boreal toads (Greenwald *et al.* 2011, pp. 56–72). Looking at these hydrologic unit of occurrences, and based on relatively current ranges described in Keinath and McGee (2005, p. 16, fig. 7), approximately 210 km (130 mi) of separation occurs in Wyoming. At least 200 km (125 mi) of separation occurs in eastern Utah and western Colorado (Greenwald *et al.* 2011, pp. 9, 56–72). Therefore, the large size and arid, inhospitable habitat of the Red Desert and arid lands to the south in Colorado and Utah likely create a geographic barrier to migrating toads.

Mitochondrial DNA analysis indicates that the SRM population is part of a more widespread evolutionary lineage that includes boreal toad populations from Utah, northeastern Nevada, southeastern Idaho, and southwestern Wyoming (Goebel *et al.* 2009; Switzer *et al.* 2009). However, since mtDNA evolves slowly, taxonomic separation based solely on mtDNA may not provide clear taxonomic distinctions. For example, a single haplotype from boreal toads in the Uinta Mountains of Utah also occurs in boreal toads in the SRM population (Goebel *et al.* 2009, p. 221). Discovery of this haplotype common to both areas led to the combination of the SRM population and the Uinta Mountain site as a minor clade—that clade is named the Eastern Rocky Mountain Minor Clade (Goebel *et al.* 2009, p. 217, figure 4). However, due to the long distance separating the sites, the occurrence of this haplotype in both areas may be a result of incomplete lineage sorting commonly found in recently isolated groups (Goebel *et al.*

2009, p. 221). In other words, boreal toads from the Uinta Mountain site and the SRM population may have interbred at one time thousands to millions of years ago, but are not likely to have interbred since then, and the similar haplotype detection is simply a feature of the slow evolutionary changes that can occur in portions of mtDNA. These statements lend support to the idea that the geographic separation of the SRM population has eliminated genetic interbreeding and the SRM population is discrete. However, further DNA (particularly nuclear DNA (nDNA)) studies are needed to provide clarification on taxonomy, before genetic evidence could be used to support genetic discreteness of the SRM population.

Nonetheless, based on its current geographic separation from other boreal toad populations, we believe there is substantial information to indicate that the SRM population may meet the DPS Policy definition of discreteness.

Evaluation of Information Provided in the Petition and Available in Service Files on Discreteness for the Eastern Population (which includes the SRM population)

As referenced above, two different studies analyzing mtDNA from boreal toads and other closely related species and subspecies conclude that toads within the SRM population and southwestern Wyoming, southeastern Idaho, northeastern Nevada, and Utah form a population of genetically similar toads termed the Eastern Major Clade (Goebel *et al.* 2009, p. 210, fig. 1) or Clade 3–1 (Switzer *et al.* 2009, p. 8, and fig. 3), which we refer to in this document as the Eastern population of the boreal toad (see the map in this notice). Both studies acknowledge that the Eastern population overlaps with areas identified as the Northwestern Major Clade (Goebel *et al.* 2009, p. 210, fig. 1) or Clade 3–2 (Switzer *et al.* 2009, fig. 3) (see the map in this notice). Therefore, absolute reproductive isolation may not currently be occurring between the Eastern population and other populations of boreal toads. However, studies suggest that the Eastern Major Clade and the Northwestern Major Clade are sufficiently different that they may represent different species (Goebel 2003 p. 7). There is a need to examine additional nDNA further north in Wyoming, in the Yellowstone area and surrounding regions, to determine if nDNA divergence parallels mtDNA divergence in boreal toads (Goebel 2003, p. 8).

Through mtDNA analysis, Goebel (2003, pp. 8–9) found greater differences between boreal toads in the Eastern Major Clade versus the Northwest Major Clade than mtDNA differences found between the Canadian toad (*Bufo hemiophrys*) and American toad (*B. americanus*), which are considered to be two separate species. Goebel *et al.* (2009, p. 15) provides further support for genetic differences, identifying the Eastern and Northwest Major Clades of boreal toads as having different haplotype groups. This mtDNA separation suggests the Eastern population of boreal toads may be a distinct species (or subspecies) from toads in the Northwest Major Clade or other taxonomic entities of boreal toads to the north and west. Haplotypes found through mtDNA analysis and microsatellite DNA analysis are differentiated enough between Clade 3–1 (corresponding to the Eastern population) and Clade 3–2 to the north that Switzer *et al.* (2009, p. 8, 23, 25) hypothesized Clade 3–1 could be its own taxonomic entity.

The petition states that the Snake River Plain in Idaho geographically separates the boreal toad populations. Boreal toads might not cross the Snake River Plain itself; however, based on genetic samples, it does not appear that the Plain is a genetic barrier (Switzer *et al.* 2009, fig 3). Genetic samples from Clade 3–2 (Switzer *et al.* 2009, fig. 3) and the Northwest Major Clade (Goebel *et al.* 2009, p. 210, fig. 1) occur north and south of the Plain, which suggests boreal toad gene flow around the Snake River Plain. The petition erroneously states that the Hell's Canyon portion of the Snake River separates boreal toads along the Idaho-Wyoming border. Although the upper end of the Snake River does occur on the Idaho-Wyoming border, Hell's Canyon is on the Idaho-Oregon border.

The petition also states that gene flow may occur to the west of the northeastern Nevada site where samples were obtained by Goebel *et al.* (2009, pp. 210, 212). However, the petition cites Noles (2010, entire), who reviewed and studied genetic and historical geologic processes (phylogeography) to explain distribution of boreal toad clades in Nevada. The study identifies some genetic sample sites and clade names for boreal toads in Nevada and states that it is reasonable to suspect that boreal toads in the Bonneville Basin are discernible from boreal toads in the Relict Dace Basin and the Lahontan Basin immediately to the west (Noles 2010, pp. 24, 50, 51). These statements lend support to the idea that the western edge of the Bonneville Basin is the northwesternmost extension of the Eastern population, as asserted by the petition. However, limited boreal toad genetic sampling in the Bonneville Basin, Relict Dace Basin, Lahontan Basin, and an unnamed basin on the northern border of Nevada make the genetic overlap issue unclear in western Utah, northern Nevada, southwestern Idaho, and eastern Oregon (Noles 2010, pp. 12, 38, 39, 50, 51).

Based on genetic data, there appears to be a continuum of boreal toad distribution from southeastern Idaho into western Wyoming and all the way to Alaska, as well as a continuum from northwestern Utah, northern Nevada, southwestern Idaho, and eastern Oregon all the way to Alaska (Goebel *et al.* 2009, p. 210, 217; Switzer *et al.* 2009, figure 3). However, the DPS policy allows for some overlap of interbreeding and states that animals do not ''require absolute reproductive isolation as a prerequisite to recognizing a distinct population segment'' and that ''recognized species * * * are known to sustain a low frequency of interbreeding with related species'' (61 FR 4722). Furthermore, as the DPS Policy explains, discreteness ''does not require absolute separation of a DPS from other members of its species, because this can rarely be demonstrated in nature for any population of organisms. This standard [adopted by the DPS Policy] is believed to allow entities recognized under the Act to be identified without requiring an unreasonably rigid test of distinctness'' (61 FR 4722). Consequently, based primarily on mtDNA genetic evidence and phylogeographic evidence, we find that the petition and our files contain substantial information that the Eastern population of the boreal toad may be discrete, despite some genetic and geographic overlap with other boreal toad populations. We will further examine this information during the status review for the 12-month finding.

Evaluation of Information Provided in the Petition and Available in Service Files on Significance for the SRM Population

Unusual or Unique Ecological Setting

The petition asserts that boreal toads in the SRM population could be significant based on unusual or unique ecological settings as described in a map of ecoregions (areas with common vegetation, soils, geology, precipitation levels, hydrology, etc.) (U.S. Environmental Protection Agency (EPA) 2011, entire). The petitioners assert that ecoregions in the SRM population are distinct from ecoregions in the Eastern population, as well as distinct from ecoregions in other areas occupied by the boreal toad. For the purposes of determining significance in a DPS analysis, we look at whether the ecological settings occupied in the area under consideration are unique or unusual to the taxon in question, not whether the setting is unique from other settings. The petitioner did not provide substantial information to indicate that the geographic area occupied by the SRM population is unique or unusual for the boreal toad taxon, as required by the DPS policy. Additionally, we found no information in our files that these settings were unique to the SRM population of the boreal toad.

The petition referenced a study that indicates that boreal toads may occur at lower elevations in Utah than in the SRM population (Hogrefe *et al.* 2005, p. 7). However, there is still overlap in elevational range of occupied habitats between boreal toads in the SRM population and in Utah; therefore, elevation does not appear to differentiate a unique ecological setting for boreal toads in the SRM population. Also, the petition notes that the ecoregions have varying (but overlapping) levels of precipitation and vary in dominant vegetation types, but again, specific habitats that boreal toads actually occupy (for example, mesic subalpine habitats) appear similar across all ecoregions. Consequently, there is not substantial evidence in the petition or in our files to support unusual or unique ecological settings as a significant factor in differentiating the SRM population from the western part of the Eastern population or from other areas throughout the range of the boreal toad.

Significant Gap in Range

The petition states the SRM population constitutes about 5 percent (or 38,894 square miles) of the range in the conterminous United States and that its loss could pose a significant gap in the range of the boreal toad. This loss, which would occur at the southeastern edge of the range, would create a gap in the range of the boreal toad in the conterminous United States. However, we do not believe this gap would be significant, due to the combination of the area being on the edge of the range and covering a relatively small area. We do not believe there is substantial information that the loss of SRM would be significant to the taxon.

Marked Differences in Genetic Characteristics

The petition suggests that boreal toads in the SRM population are significant under the DPS Policy because they comprise more diversity than currently recognized species, such as in the Canadian toad and American toad example used above by Goebel *et al.* (2009, p. 215). However, in order to be considered significant under the DPS criteria, it is not important how diverse the population is, but rather whether that diversity (e.g., that of haplotypes) differs markedly from other populations of boreal toads. Also, although Goebel *et al.*'s (2009, p. 221) statement about incomplete lineage sorting may prove accurate, we do not find there is currently enough genetic data to support the statement. Goebel *et al.* (2009, p. 15) conclude that the SRM population shares haplotypes with boreal toads in the western part of the Eastern Major Clade. Switzer *et al.* (2009, p. 26) also conclude that boreal toads within the SRM population share haplotypes with boreal toads in the western portion of Clade 3–1. In fact, both studies group boreal toads in the SRM population genetically with other toads in the Eastern population, concluding that they are part of a more widespread evolutionary lineage. Consequently, we find that current genetic analyses do not provide substantial information that the SRM population may be significant, because the SRM population does not have markedly different genes compared to the rest of the Eastern population.

Evaluation of Information Provided in the Petition and Available in Service Files on Significance for the Eastern Population

Unusual or Unique Ecological Setting

The petition asserts that boreal toads in the Eastern population could be significant based on unusual or unique ecological settings as described in a map of ecoregions (EPA 2011, entire). They assert that ecoregions in the Eastern population are distinct from other ecoregions outside of the Eastern population. For the purposes of determining significance in a DPS analysis, we look at whether the settings occupied in the area under consideration are unique or unusual to the taxon in question, not whether the setting is unique from other settings. We do not agree with the petition's assertion that ecoregions in the Eastern population are unique. Some areas within the range of the taxon may in fact be unique because of elevation, precipitation levels, and vegetative characteristics. However, we find that many of the ecoregions, and areas actually occupied by the boreal toad within the range of the taxon, are similar enough that the Eastern population cannot be characterized as unusual or unique (i.e., they occupy relatively high elevation, moist, subalpine, or boreal forest habitat). Consequently, there is not substantial evidence in the petition or in our files to support unusual or unique ecological settings as a significant factor in differentiating the Eastern population from other areas throughout the range of the boreal toad taxon.

Significant Gap in Range

The petition states the Eastern population (which includes the SRM population) constitutes approximately 20 percent of the subspecies' range in the conterminous United States and that this should be considered a significant gap in the range should boreal toads in the Eastern population become extirpated. Based on a review of the information in the petition and available in our files, there appears to be sufficient information to indicate that there may be a significant gap in the range of the species if the Eastern population were lost. We will further investigate this in our 12-month status review.

Marked Differences in Genetic Characteristics

For the Eastern population, two studies suggest through mtDNA analysis that the combination of the clades that make up the Eastern population of the boreal toad could be considered a separate species or subspecies. These hypotheses are based on different haplotypes between the clades that make up the Eastern population (Eastern Major and Clade 3–1) and the clades to its north (Northwest Major and Clade 3–2) (Goebel *et al.* 2009, pp. 215, 223; Switzer *et al.* 2009, pp. 18–26). A phylogeographic study in Nevada also suggests that boreal toads in the Bonneville Basin could be distinct from toads further to the west in Nevada, thereby supporting the idea that the Eastern population is a genetically distinct population (Noles 2010, pp. 24, 50, 51). Based on information provided in the petition and in our files on differing haplotypes between the Eastern population and clades to the north, we find that the Eastern population of boreal toad may be significant.

DPS Determination for the SRM Population

For the reasons described above, we determine that there is not substantial information in the petition and in our files to suggest that the SRM population of boreal toads may be a valid listable entity (DPS). Although this population appears geographically discrete, we did not find substantial information to suggest that it may be significant according to the standard in our DPS Policy. Therefore, we will not evaluate the status of this population further in this finding.

DPS Determination for the Eastern Population

Based on current knowledge from genetic studies and distribution information, there appears to be some genetic and geographic overlap of the Eastern population with populations of boreal toads to the north of the Eastern population. However, some genetic and geographic overlap is allowed by the DPS Policy, and we have determined that the extent of this overlap may be within the bounds of the DPS Policy. Therefore, considering information in the petition and readily available in our files, we find there is substantial information that the Eastern population of boreal toads may be a valid DPS based on sufficient genetic and geographic discreteness from the other boreal toad populations, and based on evidence of significance, including the significant gap in the range of the boreal toad that would be created if the Eastern population should become extirpated. In addition, marked (significant) genetic haplotype differences between the Eastern population and other populations of boreal toads to the north also support our determination that there is substantial information that the Eastern population may be a valid listable entity (DPS). We will further analyze the validity of this potential DPS with respect to our DPS policy during the 12-month finding.

Evaluation of Information for This Finding

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations at 50 CFR part 424 set forth the procedures for adding a species to, or removing a species from, the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In considering what factors might constitute threats, we must look beyond the mere exposure of the species to the factor to determine whether the species responds to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure and the species responds negatively, the factor may be a threat and we then attempt to determine how significant a threat it is. If the threat is significant, it may drive or contribute to the risk of extinction of the species such that the species may warrant listing as threatened or endangered as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively may not be sufficient to compel a finding that listing may be warranted. The information shall contain evidence sufficient to suggest that these factors may be operative threats that act on the species to the point that the species may meet the definition of threatened or endangered under the Act.

In making this 90-day finding, we evaluated whether information regarding threats to the Eastern population of the boreal toad, as presented in the petition and other information available in our files, is substantial, thereby indicating that the petitioned action may be warranted. Our evaluation of this information is presented below.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Information Provided in the Petition

The petition states that water management, roads, livestock grazing, recreation, timber harvest, residential and commercial development, pollutants, and energy and minerals management are all activities that destroy, modify, or curtail the boreal toad's habitat or range. The petitioners believe that any of these activities could contribute to the decline of the boreal toad.

Water Management—The petition cites several studies to show that water management can lead to direct habitat loss, habitat fragmentation, and detrimental alteration of natural hydrological regimes, through a number of activities, including draining or filling of wetlands, water diversion for municipal or agricultural purposes, dam and reservoir construction, dewatering of habitats, bank stabilization, and stream channelization (Loeffler 2001, p. 12 ; McGee and Keinath 2004, p. 37; Hogrefe *et al.* 2005, p. 19; Stoddard *et al.* 2005, p. 6). The petition also states that extended hydroperiods of wetlands can increase densities of invertebrate predators and establishment of predatory fishes (Scott 1996, pp. 45–46; Skelly 1996, pp. 599–604).

Roads—The petition states that roads cause habitat fragmentation, prevent migration, cause mortality, and alter water flow that sustains aquatic habitats (Lehtinen *et al.* 1999, p. 2; Loeffler 2001, p. 12; Hogrefe *et al.* 2005 p. 17). The petition also states that amphibians in general are particularly vulnerable to road mortality. The petition states that other detrimental factors may include pollutants, erosion and sedimentation, vibrations, and noise. The petition cites several additional studies to support these claims, but these references were not provided to us or readily available in our files. One article and one personal communication referenced in the petition state that several boreal toad mortalities have been observed, but other references either do not provide specific information or appear to be general and would not provide information specific to the boreal toad.

Livestock Grazing—The petition states that livestock trample boreal toads and their habitat. Trampling of habitat could cause further mortality to boreal toads from loss of vegetative cover resulting in desiccation (Bartelt 2000, pp. 98; Hogrefe *et al.* 2005, p. 15). The petition also provides information to suggest that livestock grazing may cause declines in water quality from excess nutrients, reduction in vegetation that helps filter water, and reduced survival of eggs and tadpoles from increased siltation, water temperatures, and fecal contamination (Loeffler 1998, p. 54; McGee and Keinath 2004, pp. 33–34; Hogrefe *et al.* 2005, p. 15). The petitioners argue that insect abundance (toad prey) also may be reduced by livestock grazing (Fleischner 1994, pp. 631–632). The petitioners state that prairie-dog or other rodent control programs for livestock management reduce availability of burrows for overwintering toads (Sharps and Uresk 1990, pp. 339–345). The petition also suggests that compaction of soils may potentially limit the availability of burrows that help prevent desiccation and freezing of toads, that overutilization of tall herbaceous cover may make adult toads more susceptible to predation, and that grazing contributes to a decline in beaver populations that may, in turn, result in less boreal toad habitat. The petitioners did not provide references to support most of the above claims, and we do not have data readily available in our files to support such claims.

Recreation—Recreation is cited in the petition as impacting amphibians through loss of eggs, tadpoles, metamorphs, and adults due to trampling, vehicle impacts, habitat degradation, an increase in predators attracted to human refuse, and transfer of pathogens between boreal toad populations (Hogrefe *et al.* 2005, p. 17). The petition states that human handling and pet-related mortality of boreal toads also may occur. The petition provides examples of where some of these activities have impacted boreal toads, and cites references that were not available to us in our files.

Timber Harvest—The petition states timber harvest may cause (1) mortality through crushing by equipment, (2) interruption of dispersal from breeding sites, or of late-summer dispersal of adults into uplands, (3) soil compaction that limits the availability of burrows used for overwintering hibernacula, (4) a reduction of available refugia through burning of slash piles and downed woody materials, (5) sedimentation that could disturb habitat, and (6) the spread of nuisance species. The petition states that any timber harvest activity that affects wetlands could have negative impacts to the boreal toad (Loeffler 1998, pp. 56–57; Bartelt 2000, pp. 20–27, 74–77; McGee and Keinath 2004, pp. 32–33). However, only one of the references available to us on this topic was specific to the species, showing that effects to boreal toads from interruption of dispersal by timber harvest have been documented (Bartelt 2000, pp. 20–27, 74–77).

Residential and Commercial Development—The petition states that residential and commercial development have potentially caused extirpation of boreal toads in several areas in Utah and Colorado (Thompson *et al.* 2004, p. 257).

Pollutants—The petition states that pollutants including herbicides, insecticides, and piscicides are harmful to amphibians (Loeffler 2001, p. 13; Hayes *et al.* 2002, pp. 5476–5479). The petition also states that high salinity concentrations may affect toad equilibrium and that a high proportion of streams in the range of the Eastern population of boreal toad have high salinity (Dole *et al.* 1985, pp. 645–648; Stoddard *et al.* 2005, p. 40).

Energy and Minerals Management—The petition states that energy and minerals management causes habitat loss and fragmentation from new roads, well pads, pumps and other facilities, and utility lines, and an increase in human presence from vehicle traffic and construction activity (U.S. Bureau of Land Management (BLM) 2005, pp. 3–29).

Evaluation of Information Provided in the Petition and Available in Service Files

Water Management—Alteration of natural hydrology and hydrologic processes, such as removal of water sources, shortening or lengthening water availability, and flooding large areas of habitat or dispersal corridors could cause impacts to the boreal toad (Loeffler 2001, p. 12; Hogrefe *et al.* 2005, p. 19). It is possible that extended hydroperiods of water bodies could increase densities of invertebrate predators and allow establishment of predatory fishes. It also is possible that water manipulation could decrease rates of boreal toad reproduction and recruitment (Scott 1996, pp. 45–46; Skelly 1996, pp. 599–604; Semlitsch 2002, pp. 621–623; McGee and Keinath 2004, p. 37). The creation of Lefthand Reservoir in Boulder County, Colorado, flooded a large wetland, forcing boreal toads to its margins where habitat may not have been as suitable (Campbell 1970a, p. 7; Hammerson 1999, p. 92). Reservoirs may not have suitable shallow water for breeding, and open water replaces foraging habitat around previously existing wetlands (Hammerson 1999, p. 92). However, the information in the petition and in our files did not provide any substantial information or analyses to suggest that these effects are occurring in a widespread basis in the Eastern population of boreal toads.

The petition states that a substantial proportion of streams located within the range of the Eastern population of boreal toads have been impacted by disturbance, and cites a study illustrating an average 30–40 percent disturbance of stream corridor riparian areas, about 10 percent disturbance of riparian vegetation, and 10–20 percent disturbance of streambed stability by stressors in the Southern Rockies and Northern Rockies ecoregions (Stoddard 2005, p. 40, fig. 15). The stream corridor riparian area category does indicate a moderate amount of disturbance to potential boreal toad habitat loss and fragmentation. However, the number and extent of streams in this study that were occupied by boreal toads is unknown, so the extent of impact is indeterminable.

The petitioners state that wetland losses have occurred throughout Utah and are expected to continue due to human population growth (Lee 2001, p. 4). There are numerous wetlands and water sources within the range of the boreal toad that have not been impacted, but there has been alteration of riparian and wetland habitat and hydroperiods due to water development and use. We believe this issue is the most likely activity under Factor A to cause impacts to the boreal toad. However, the petition and the information in our files does not detail the extent of wetland or riparian habitat alteration as it corresponds to effects on boreal toad habitat. The petition does not provide an analysis of water management impacts to boreal toads. Consequently, we find that localized impacts from water management activities may occur, but the petition and information in our files does not present substantial scientific or commercial information indicating that water management activities are a threat for the Eastern population of the boreal toad.

Roads—Roads could cause direct mortality by vehicle strike as well as direct loss of habitat, fragmentation, sedimentation, and alteration of hydrology, and could potentially limit dispersal and gene flow (Lehtinen *et al.* 1999, pp. 1–12; Loeffler 2001, p. 12; Hogrefe *et al.* 2005, p. 17). However, while the petitioners mapped major roads in the range of the boreal toad, they provided limited specific evidence of road impacts to boreal toad populations (Hogrefe 2005, p. 17; Greenwald *et al.* 2011, pp. 26, 72). The references referred to by the petition as supporting impacts from roads were general in nature and did not speak directly to the boreal toad or its habitat. Although there are some heavily traveled roads in or near boreal toad habitat, the majority of roads are less-traveled dirt roads that we do not believe cause a high level of mortality or other impacts to boreal toads. We find that localized impacts from roads may occur but the petition and information in our files does not present substantial scientific or commercial information indicating that roads may threaten the Eastern population of the boreal toad.

Livestock Grazing—Livestock grazing can occasionally cause direct mortality to boreal toads (Bartelt and Peterson 1996, p. 14; Bartelt 2000, p. 98; Hogrefe *et al.* 2005, p. 15). Additionally, grazing can cause boreal toad habitat destruction and degradation through eating and trampling of vegetation and possible water quality reduction through bank erosion and water contamination (Fleischner 1994, pp. 631–632; Loeffler 1998, p. 54; Bartelt 2000, pp. 98, 20–27, 74–77; McGee and Keinath 2004, pp. 33–34; Hogrefe *et al.*

2005, p. 15). Clear-cutting (removal of all trees in an area) has been shown to adversely affect boreal toads by creating open spaces that are too dry (and presumably too cold at night) for toads (Bartelt 2000, pp. 20–27, 74–77). If livestock are removing vegetation in large areas, adverse conditions similar to those resulting from clear-cuts could occur. However, the references in the petition and additional references in our files (Bartelt and Peterson 1996, entire) only mention occasional direct effects to the boreal toad and only the possibility of widespread habitat threats. We find that localized impacts from grazing may occur, but the petition and information in our files do not present substantial scientific or commercial information indicating that grazing may be a threat to the Eastern population of boreal toad.

Recreation—Recreation from camping, hiking, biking, fishing, and off-highway vehicle use could impact boreal toad habitat and bring increased predation and the chance of pathogen introduction (Loeffler 1998, p. 51). Potential effects from these activities include transfer of disease, including Bd, into uninfected habitats, along with trampling, loss of vegetation, reduced water quality, and loss of habitat (Hogrefe *et al.* 2005, pp. 15, 17). Human activities around boreal toad breeding sites could increase the presence of ravens and jays, which could increase predation on boreal toads. However, we are not aware of studies that specifically researched effects of recreation on boreal toads. We find that localized impacts from recreation may occur, but the petition and information in our files do not present substantial scientific or commercial information indicating that recreation may be a threat to the Eastern population of boreal toad.

Timber Harvest—Timber harvest activities, especially clear-cuts, can have detrimental effects to the boreal toad by interrupting dispersal corridors, causing sedimentation of streams, causing impacts to wetland and riparian vegetation used by toads, and affecting habitat by prescribed burning of slash piles or downed woody material (Bartelt and Peterson 1994, pp. 18–19; Loeffler 1998, pp. 56–57; Bartelt 2000, pp. 20–27, 74–77; McGee and Keinath 2004, pp. 32–33). Timber harvest equipment can cause direct mortality and compaction of soils that reduce burrow availability for shelter or overwintering (Loeffler 1998, pp. 56–57; McGee and Keinath 2004, pp. 32–33). Although local impacts to habitat may occur from slash pile or downed woody material burning in timber harvest areas, prescribed burning or wildfires can promote longevity of wetland areas that boreal toads need by preventing build-up of vegetation and subsequent succession to other habitat types (Russell *et al.* 1999, pp. 374–384). We find that localized impacts from timber harvest activities may occur, but the petition and information in our files does not present substantial scientific or commercial information indicating that timber harvest activities occur frequently enough that they may be a threat to the Eastern population of boreal toad.

Residential and Commercial Development—Some boreal toad habitat loss could be attributed to development on the Wasatch Front between Salt Lake City and Provo, Utah; rapid population growth in this area has likely contributed to boreal toad habitat impacts and possible extirpations (Lee 2001, p. 4; Thompson 2004, p. 257). Ski areas and associated residential development in Colorado also were identified in the petition as causing habitat loss or degradation. The petition did not cite any references on the effects of ski areas, but an article on home ranges of boreal toads documents the potential impacts of ski area development by mentioning ski area proximity and related county setbacks in Summit County, Colorado (Muths 2003, p. 163). Ski area development and associated housing have likely impacted localized areas, but boreal toads currently face little threat from residential and commercial development due to the higher elevation habitat they occupy. We find that localized impacts from residential and commercial development may occur, but the petition and information in our files do not present substantial scientific or commercial information indicating that residential or commercial development may be a threat to the Eastern population of boreal toad.

Pollutants—There are observations and studies describing potential impacts to the boreal toad from mine runoff and acidification (Porter and Hakanson 1976, pp. 327–331; Corn *et al.* 1989, entire; Corn and Vertucci 1992, entire; Loeffler 1999, pp. 31–32; Jackson 2006, pp. 58–59). However, impacts are likely localized. Although it was hypothesized that a short-term acidic pulse from snowmelt could produce effects to amphibians, acidification was not found to be a factor in regional amphibian declines in the Rocky Mountains (Corn and Vertucci 1992, p. 367). Another study demonstrated that pH would have to be below 4.9 to produce negative effects to boreal toad embryo survival, but pH in the elevations common for boreal toad occurrence is typically between 7 and 6 (Corn *et al.* 1989, pp. 19, 20, 28). Therefore, information in the petition and in our files suggests that localized impacts from pollutants may occur, but there is not substantial information to demonstrate that the impacts are pervasive enough that they may be a threat to the Eastern population of the boreal toad.

Studies have illustrated the effects of pesticides and herbicides on amphibians, and deposition by drift can occur (Berrill *et al.* 1994, p. 663; Hayes *et al.* 2002, pp. 5476–5479; Fellers *et al.* 2004, p. 2176; Relyea 2005, p. 626). However, to our knowledge there is limited application of pesticides or herbicides in or near boreal toad habitat. Forest management activities such as fire retardant drops are infrequent, and piscicide application also is infrequent. In addition, we do not agree with the petitioners that a high proportion of streams in the range of the Eastern population of the boreal toad have high salinity levels (Stoddard 2005, p. 40, fig. 15). In fact, we believe they misinterpreted information in their reference source, because ecoregion locations (described in the reference) where boreal toads primarily occur (Southern Rockies, Northern Rockies, and Northern Xeric Basins) have very low salinity (Stoddard 2005, p. 40, fig. 15). Salinity from road salts could impact localized breeding sites, but we expect the occurrence of these impacts is rare across the range and would likely occur along heavily traveled roads only. Overall, we find that localized impacts from pollutants may occur, but the petition and information in our files do not present substantial scientific or commercial information indicating that pollutants may be a threat to the Eastern population of boreal toad.

Energy and Minerals Management—Energy and mineral development can cause habitat loss and fragmentation from roads, utility lines, and other facilities, and can increase human presence in mining areas. As the petition points out, hardrock mines in Colorado may impact boreal toads, but boreal toads continued to inhabit the Urad/Henderson Mine in large numbers until Bd arrived there in 1999 (Loeffler 1999, pp. 31–32; Jackson 2006, pp. 27, 58–59). In fact, there is speculation that Bd-infected boreal toads at the Urad/Henderson Mine may have had better survival from the infection due to inhabiting water with mine effluent than boreal toads not inhabiting waters in the effluent area (Jackson 2006, pp. 58–59). Mining may increase human presence in boreal toad habitat and some mortality may occur from vehicles or people, but with the general decline in hardrock mining activity over the last several decades, we believe the risk of mortality from mining-related activities is low.

We also are not aware that oil and gas development is a widespread activity in boreal toad habitat. In Colorado, where extensive oil and gas development has occurred, an extremely small amount of oil and gas development occurs in boreal toad habitat and the majority of boreal toad habitat is located in areas that have low to no potential for oil and gas development (Gunnison Sage-grouse Rangewide Steering Committee 2005, p. 130; Colorado Greater Sage-grouse Steering Committee 2008, p. 112). We find that localized impacts from energy and minerals management may occur, but the petition and information in our files do not present substantial scientific or commercial information indicating that energy and minerals management may be a threat to the Eastern population of the boreal toad.

Summary for Factor A

Based on the information provided in the petition, as well as other information readily available in our files, we find that the petition does not present substantial scientific or commercial information indicating that the Eastern population of the boreal toad may warrant listing due to the present or threatened destruction, modification, or curtailment of the species' habitat or range. Although each of the issues evaluated under Factor A may impact the Eastern population of the boreal toad locally, the information in the petition and in our files does not indicate that these rise to the level of a threat to the population. There is no information presented in the petition or contained in our files that the threats described under Factor A cumulatively threaten the Eastern population of the boreal toad. However, we will evaluate this factor and cumulative effects of the threats described under this factor more thoroughly during the 12-month status review if we determine that a valid DPS of boreal toad exists.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The petition states there is little information on the extent of boreal toad collection or harvesting (McGee and Keinath 2004, p. 37). Some boreal toads, eggs, or tadpoles have been collected by universities, State wildlife agencies, zoos, and other institutions for propagation, translocation, genetic research or other scientific study, or educational purposes. However, information in our files shows that entities involved in these activities in the SRM population area have developed protocols to avoid or minimize mortality or injury to boreal toads (Scherff–Norris 1997, entire; Loeffler 2001, pp. 36–53). Additionally, the Utah Conservation Plan provides general procedures to minimize impact of collection activities and outlines plans for development of protocols (Hogrefe *et al.* 2005, pp. 28–38). Due to collection and handling procedures implemented by these entities, and the lack of known collection pressure from the public, we do not consider overutilization of the boreal toad to be occurring. Based on our evaluation, neither the petition nor information in our files presents substantial scientific or commercial information to indicate that overutilization for commercial, recreational, scientific, or educational purposes may present a threat to the Eastern population of the boreal toad such that the petitioned action may be warranted. However, we will evaluate this factor more thoroughly during the 12-month status review if we determine that a valid DPS of boreal toad exists.

C. Disease or Predation

Information Provided in the Petition

Disease—The petition states that the chytrid fungus (Bd) is the primary pathogen of concern for the Eastern population of the boreal toad (Fellers *et al.* 2001, pp. 945, 952; McGee and Keinath 2004, pp. 23–24; Hogrefe *et al.* 2005, p. 13). The petition states that Bd attacks the skin of boreal toads and can cause chytridiomycosis (the disease that can result from Bd infection), resulting in 90–100 percent mortality (McGee and Keinath 2004, pp. 43–44). The exact mechanism of mortality caused by Bd infection is not understood, but possible mechanisms include disruption of water, oxygen, and ion exchange and secretion of toxins from the Bd associated with chytridiomycosis (Berger *et al.* 1998, p. 9036).

The petition also claims that red-leg disease (*Aeromonas hydrophila*), a fungus called *Saprolegnia ferax,* and a trematode (*Ribeiroia ondatrae*) have all been documented to cause mortality or malformations in amphibians and also could impact the Eastern population of boreal toads (Johnson *et al.* 2001, pp. 370–379; Kiesecker *et al.* 2001, entire; Hogrefe *et al.* 2005, p. 14). The petition states that nonnative species, such as bullfrogs (*Rana catesbeiana*) and certain species of fish, may impact the boreal toad by transmitting pathogens, including Bd and *Saprolegnia ferax* (Kiesecker *et al.* 2001, p. 1069; Schloegel *et al.* 2010, p. 53).

Predation—The petition states that, despite boreal toad adults' having toxic skin secretions, boreal toads have many native predators that are suspected of depressing toad populations (Arnold and Wassersug 1978, entire; Flier *et al.* 1980, entire; Beiswenger 1981, entire; Brodie and Formanowicz 1987, entire; Olson 1989, entire). The petition states that nonnative predators, such as trout or bullfrogs, also may reduce populations of boreal toads (Bahls 1992, pp. 183, 191; McGee and Keinath 2004, pp. 38–39).

Evaluation of Information Provided in the Petition and Available in Service Files

Disease—Bd was first identified in the late 1990s from a captive blue poison dart frog (*Dendrobatis azureus*) (Longcore *et al.* 1999, entire). Since then, Bd has been reported in numerous species of amphibians worldwide and is most likely a recent introduction to North America (Berger *et al.* 1999, p. 29; Lips *et al.* 2003, entire). However, Bd has been present since at least the early 1970s in America. A specimen from Colorado preserved in 1974 was tested for Bd and was found to have the fungus present (Hogrefe *et al.* 2005, p. 14). As stated above, Bd attacks the skin of boreal toads and may cause chytridiomycosis, which can result in serious disruption of cutaneous respiration and osmoregulation (Berger *et al.* 1998, p. 9036).

Boreal toads on the Paunsaugunt Plateau in southern Utah were reported to be infected with Bd in 2005, and chytridiomycosis is the suspected cause of boreal toad mortalities in this population (Hogrefe *et al.* 2005, pp. 14, 26). The Paunsaugunt Plateau (represented by up to seven sites comprising one or two breeding populations) was the only area out of six areas in the UDWR's Southern Region that was positive for Bd infection as of 2009 (UDWR 2010, p. III–3). The Paunsaugunt Plateau had only one adult toad observed in 2009 at one out of seven sites monitored on the Plateau, although a couple of other sites on the Paunsaugunt Plateau had tadpoles observed (UDWR 2010, pp. III–3, 5). The low number of toads suggests that Bd has affected toads on the Paunsaugunt Plateau.

In 2008, 77 Bd swabs (DNA samples taken for analysis of Bd presence or absence) were taken from boreal toads at Strawberry Reservoir in the Central Region of the Utah Division of Wildlife Resources, with 38 of those samples (49 percent) testing positive for Bd (UDWR 2010, p. II–4). In 2009, 105 toads were detected at 3 sites at Strawberry Reservoir; however, the impacts of Bd on boreal toad recent population trends are uncertain (UDWR 2010, pp. II–3, II–10). In the Northeast Region of the UDWR, only 1 of 27 Bd swabs taken in 2008 tested positive for Bd (UDWR 2010, p. IV–4). Although some swabs are positive for Bd infection, Bd test results among regions in Utah are variable, and it is unknown whether or not Bd is causing declines in boreal toad populations there. However, it is clear that the infection is present across Utah.

Surveyors and researchers in the SRM population collected 417 samples from 46 sites across Colorado in 2003, and subsequent analysis detected 33 toads at 8 sites with Bd (Jungwirth, 2004, p. 53). It also was discovered from the study that, at sites with Bd, adult and juvenile toads had a 77 percent prevalence rate of infection (Jungwirth 2004, p. 54). Metamorphs often do not test positive at known Bd positive sites, and it is theorized that metamorphs may not have enough exposure time to the terrestrial environment to become infected with Bd (Jungwirth 2004, p. 54). Furthermore, at toad breeding sites tested through the 2007 field season, 22 breeding sites tested positive for Bd, 35 tested negative, and 22 additional sites were not tested (Jackson 2008, p. 6).

Even though Rocky Mountain National Park (RMNP) is one of the most protected environments within Colorado, boreal toad populations have declined in the park (Corn *et al.* 1997, pp. 40, 42). Four sites were monitored in RMNP from 1990 to 2001, and significant declines of boreal toads were noted at two of the sites (Kettle Tarn and Lost Lake), although all sites declined (Muths *et al.* 2003, p. 5). Six adult toads that were suitable for histologic analysis all had Bd detected on them, and another four of six that had preliminary molecular analysis conducted on them were also determined to have Bd infections (Muths *et al.* 2003, p. 8). Based on analysis for other diseases, it was determined that Bd was the certain cause of decline (Muths *et al.* 2003, pp. 8–9). Evidence of the decline is supported by monitoring data showing that Lost Lake had 100–300 toads present from 1991 to 1998, but fell to 30 or fewer since then (Jackson 2008, p. 57). Kettle Tarn had a hundred or more toads from 1991 through 1995 but exhibited a similar precipitous decline afterwards (Jackson, 2008, p. 58).

Bd testing has not been conducted in the remaining population in southeastern Wyoming (Jackson 2008, p. 91). However, as with the rest of the SRM population, Bd is the suspected cause of declines in southeastern Wyoming (Jackson 2008, p. 4). As stated above, boreal toads were extirpated in New Mexico for many years, but reintroduced there in 2008 and 2009. However, in 2009 seven boreal toads from the 2008 release were recaptured, but six of the seven tested positive for Bd (NMDGF 2010, p. 3). This indicates that chytridiomycosis probably extirpated them in the past, and chance of survival of reintroduced toads is low. We currently have no information on Bd occurrence in southeastern Idaho, northeastern Nevada, or southwestern Wyoming.Overall, Bd appears to be widespread, and is known to occur in the SRM and Utah.

Given its widespread distribution in the SRM area, Utah, and around the world, it is likely present in the rest of the Eastern population and is almost assuredly the primary reason for declines observed in boreal toads in the Eastern population.

The fungal disease *Saprolegnia ferax* was spread to boreal toads from rainbow trout (*Oncorhynchus mykiss*) experimentally infected with *S. ferax* (Kiesecker *et al.* 2001, p. 1064). Although transmission of the disease from fish to boreal toads can occur, we have no information indicating that *S. ferax* is prevalent in the wild or has caused boreal toad declines in the wild.

We also have no information in our files to suggest that the trematode *Ribeiroia ondatrae* poses a threat to the boreal toad. The petitioners provided one article cited in the petition that found high frequencies (40–85 percent) of severe limb malformations in surviving western toads (*Anaxyrus boreas*) and decreased survivorship (42 percent) in toads with the heaviest treatment of trematodes in an induced laboratory experiment (Johnson et al. p. 370). However, effects of the trematode to wild boreal toads is not known, and the petition admits that further study is needed before any conclusions can be drawn on effects of the trematode to the boreal toad. Consequently, the petition did not present substantial information to suggest that the trematode may be a threat.

In conclusion, studies and information presented above illustrate that Bd may be the major factor in the decline of the boreal toad and that it poses a significant threat to the Eastern population of the boreal toad (Loeffler 2001, p. 13; Hogrefe *et al.* 2005, pp. 13–14). We find that the petition and information in our files present substantial scientific or commercial information indicating that disease, specifically Bd resulting in chytridiomycosis, may be a threat to the Eastern population of the boreal toad.

Predation—The petition and information in our files show that adult boreal toads have several avian, mammalian, and reptilian predators (Olson 1989, entire; Hammerson 1999, p. 97; Livo 1999, p. 1). Avian, reptilian, insect, and even other amphibian predators of tadpoles and newly metamorphosed boreal toads also have been recorded (Beiswenger 1981, entire; Hammerson 1999, p. 98). Both garter snakes (*Thamnophis elegans*) and spotted sandpipers (*Actitis macularia*) are often encountered at boreal toad breeding sites in Colorado (Lambert 2003, pp. 22, 24, 77). At Brown's Creek in Colorado, garter snakes are suspected to be responsible for poor survivorship of boreal toad tadpoles (Lambert 2003, pp. 24, 77). It is likely that poor survivorship from predation occasionally results, but other than Lambert (2003, p. 22, 24, 77), we have no evidence that this occurs often enough or to an extent that it suppresses survival at breeding sites or breeding populations to a point that it may threaten the Eastern population of the boreal toad.

Nonnative predators, such as bullfrogs or stocked trout, were asserted by the petitioners to cause impacts to the boreal toad. We do not have any information that suggests that bullfrogs prey on boreal toads, since bullfrogs have never been documented in boreal toad habitat. Trout have been stocked in many lakes in the western United States, many of which were fishless prior to stocking (Bahls 1992, p. 183). The presence of stocked trout has been found to exclude frogs from lakes in the Sierra Nevada Mountains (Bradford 1989, pp. 776–777). However, laboratory experiments have indicated that American toad (*Bufo americanus*) tadpoles may be less palatable than chorus frog tadpoles (*Pseudacris triseriata*) to certain species of fish (Voris and Bacon 1966, p. 597) and we suspect that boreal toad tadpoles have similar toxins as the American toad. Additional evidence is that cutthroat trout (*Salmo clarkii*) mouthed then rejected boreal toad eggs that were fed to them (Licht 1969, p. 296). Although trout may injure boreal toad eggs or tadpoles by mouthing them, it appears that predation on boreal toads may be limited, due to the trout's avoidance of toxins in the eggs and tadpoles.

Localized predation from native or nonnative predators may sporadically occur and could occasionally cause declines or extirpation of breeding sites or breeding populations. However, we find that the petition and information in our files does not present substantial scientific or commercial information indicating that predation may rise to the level of a threat to the Eastern population of the boreal toad.

Summary for Factor C

Based on our evaluation, the petition and information in our files present substantial information that listing the Eastern population of the boreal toad due to disease may be warranted. Localized predation may cause effects to breeding sites or breeding populations, but the petition and information in our files do not present substantial information that listing the Eastern population due to predation may be warranted. However, we will evaluate this factor more thoroughly during the 12-month status review if we determine that a valid DPS of boreal toad exists.

D. The Inadequacy of Existing Regulatory Mechanisms

Information Provided in the Petition

The petition states that the boreal toad has been State-listed as endangered in Colorado and New Mexico (NMDGF 1988, p. 1; CDOW 1993, p. 2). The petition also states that the toads are designated as a State Sensitive Species in Utah. In Wyoming, the boreal toad is designated as a Native Species Status 1, which means the species and habitat are declining (McGee and Keinath 2004, p. 46). The petition states that the designations in Utah and Wyoming garner no legal or regulatory weight. The petition also states that boreal toads are designated as nongame species in Idaho, protecting them from collection. There is no designation for the boreal toad in Nevada.

The petition states that a Colorado recovery plan was completed in 1994, and a recovery plan for New Mexico was completed in 2006 (Nesler and Goettle 1994, entire; Pierce 2006, entire). The petition states that in Utah a conservation plan for the toad also has been completed (Hogrefe *et al.* 2005, entire). The petition adds that Idaho and Nevada do not have conservation plans for the boreal toad.

The petition states that the majority of boreal toad habitat in the Southern Rocky Mountains is on U.S. Forest Service (USFS) land. The petition also points out that the USFS in both Region 2 (Colorado and southeast Wyoming) and Region 3 (New Mexico) classifies the toad as a sensitive species. However, USFS Region 4 (western Wyoming, southern Idaho, Nevada, and Utah) does not classify the toad as a sensitive species. The petition mentions that only two forests, the White River National Forest and Medicine Bow National Forest (in Colorado and Colorado/Wyoming, respectively), have forest plans that contain standards and guidelines for managing the boreal toad. However, the petition notes that the two forests only cover a small portion of the range of the toad and the forest plans do not adequately address all the threats to the toad. The petition also states that the Uintah National Forest, which covers a small area of the range of the Eastern population of the boreal toad, has a voluntary guideline to protect boreal toad habitat from disturbance (trampling) during the breeding season.

The BLM classifies the boreal toad as a sensitive species in Wyoming, Colorado, Utah, and Idaho. The petition points out that a State-led Boreal Toad Recovery Team comprised of State and Federal agencies, and an associated Technical Advisory Group comprised of university, State, Federal, and local government staff was formed and produced a conservation plan for the boreal toad in the Southern Rocky Mountains in 1998 (Loeffler 1998, entire) and revised the plan in 2001 (Loeffler 2001, entire).

The petition states that none of the State, USFS, or BLM classifications or recovery or conservation plans are adequate to protect the boreal toad, because they do not protect habitat, they carry no legal or regulatory weight, and they have not been shown to have improved the status of the toad. For example, the petition states that the Utah Conservation Plan does not address all threats to the boreal toad, such as Bd, and Bd has been detected in toads in Utah. The petitioners also considered conservation agreements, and found the specified actions to be implemented by involved parties within the SRM conservation plan were vague and provided little protection to the boreal toad. The petition states that even if all actions in the SRM conservation plan were accomplished, it still would not adequately address the impacts of Bd on boreal toads.

Evaluation of Information Provided in the Petition and Available in Service Files

State listings in Colorado and New Mexico mean that possession of the boreal toads is prohibited. In Idaho, the nongame regulations prohibit possession of more than four boreal toads (Idaho Administration Procedures Act 2010, p. 4). The boreal toad was designated as a State Sensitive Species in Utah in 1997 (Hogrefe et al. 2005, p. 2). However, neither the Utah nor Wyoming sensitive species designations protect the toad from possession. Obviously, the lack of status in Nevada does not prevent possession of the toad there. However, we have no information on whether collection and possession of the boreal toad in any of the States is impacting the toad.

The Colorado Department of Parks and Wildlife (formerly Division of Wildlife), Wyoming Game and Fish, NMDGF, and UDWR have led or been instrumental in development of the State and SRM conservation plans, along with the USFS, U.S. Geological Survey, National Park Service, and BLM. Since the boreal toad was State listed in Colorado, considerable effort and funding have gone towards research, management, captive breeding, and translocation or repatriation of boreal toads in Colorado, Wyoming, and New Mexico (the SRM population). University staff, the U.S. Geological Service, zoos, and others also have been instrumental in research into declines of the boreal toad and propagation of the toad.

Despite development of the conservation plans (which are voluntary and not regulatory in nature), and the designations by different State and Federal agencies, the research and management actions that have occurred, and the standards and guidelines put into place by the USFS, there has been little success in conserving the boreal toad because of the difficulty of arresting Bd-caused declines. However, the overwhelming factor in the boreal toad's decline is chytridiomycosis caused by Bd, which will likely affect the toads regardless of what regulatory protections are in place.

Summary for Factor D

Even though the Federal agencies have not addressed or implemented boreal toad management through all of their forest plans or resource management plans, they do have guidance through their sensitive species designations to manage for the toad. There have been management actions for the toad carried out on Federal lands, but the Service does not currently have information on the extent of implementation and effectiveness of these actions. The States within the Eastern population lack regulatory authority to protect the toad's habitat. However, as stated above in Factor A, we did not find substantial information to show that habitat destruction, modification, or curtailment currently threaten the toad. Consequently, there is not substantial information to indicate that regulations protecting habitat are inadequate. Similarly, issues under Factors B, C, and E do not currently appear to need further regulatory mechanisms or would not be resolved by further regulatory mechanisms. Some of the States have regulations that prohibit or limit possession of boreal toads; however, there is no information to suggest that collection and possession of the boreal toad in any of the States is impacting the toad. Consequently, there is not substantial information to indicate that State regulations prohibiting collection and possession, or lack thereof, are inadequate.

Nonetheless, as both we and the petitioners recognize, Bd may be the overriding threat to the boreal toad, and we believe regulatory mechanisms are not capable or have limited capability to reduce the existing threat from Bd. Based on our evaluation, neither the petition nor information in our files presents substantial information that listing the Eastern population of boreal toad due to inadequacy of existing regulatory mechanisms may be warranted. However, we will evaluate this factor more thoroughly during the 12–month status review if we determine that a valid DPS of boreal toad exists.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Information Provided in the Petition

Isolation—The petition states that many populations of boreal toad are small and isolated (Hogrefe *et al.* 2005, p. 15). Isolation and small population size can preclude genetic interchange and recolonization of habitat in the face of impacts such as Bd or long-term land management changes (Carey *et al.* 2005, pp. 235, 236). Lack of gene flow also may cause loss of genetic variability (Wright 1931, pp. 98–102), causing inbreeding depression. The petition states that random events, environmental factors, or human impacts may cause extirpation of small, isolated populations.

Climate Change—The petition states that since boreal toads are ectotherms (require heat from the sun or outside sources to warm selves), their body temperature varies with their surroundings. The petition states (?) boreal toad reproductive behavior and boreal toad abundance may be affected by temperature changes resulting from climate change (Blaustein and Wake 1995, pp. 2–4; Blaustein *et al.* 2001, p. 1808). The petition also states that warmer temperatures may allow for the spread of disease, especially in higher elevations where currently disease may not be as prevalent. The petition states drought and early or late season freezing temperatures caused by climate change may dry up breeding pools and cause mortality before or after hibernation (McGee and Keinath 2004, p. 41). The petition states that warming will limit activity of toads in different habitats (Bartelt *et al.* 2010, p. 2675). The petition also states that effects of climate change may have already been observed through increasingly earlier breeding due to warmer temperatures or reduced precipitation (Blaustein *et al.* 2001, p. 1806; Corn 2003, p. 624).

Ultraviolet Radiation—The petition states that degradation of the ozone may be causing increases in ultraviolet-B (UV–B) radiation (Stolarski *et al.* 1992, p. 342; Blumthaler *et al.* 1997, p. 130). The petition states the boreal toad may be susceptible to UV–B radiation due to not having protective hair or feathers, and not having protective shells on their eggs, which are laid in shallow water (Blaustein *et al.* 1994, p. 1791; Corn 1998, p. 19). Additionally, the petition states that photolyase, an enzyme that repairs UV–B damage, is lower in boreal toads than in some frogs and may cause lower hatching success in boreal toads (Blaustein *et al.* 1994, p. 1794). However, the petition also acknowledges that some studies show UV–B radiation is not a factor in hatching success of red-legged frogs (*Rana aurora*) or boreal toads (Blaustein *et al.* 1996, p. 1401; Corn 1998, pp. 22–23; Loeffler 2001, p. 12).

Invasive Species—The petition discusses invasive species under Factor E, but since the discussion focuses on disease transmission and predation by invasive species, we address this under Factor C, *Disease or Predation,* above.

Evaluation of Information Provided in the Petition and Available in Service Files

Isolation—Isolation or small population size could cause extirpation of boreal toad breeding colonies through habitat loss or fragmentation or other human or environmental factors (such as Bd infection), random events, or genetic problems. Microsatellite nDNA analysis suggests that populations of boreal toads within the Eastern population are isolated from one another, with little gene flow, and that this could potentially cause genetic problems (Switzer *et al.* 2009, pp. 23, 25). Additional information suggests that boreal toad populations in Utah are separated from each other due to long-term climate change (over the last 10,000 years) and human development at lower elevations resulting in genetic problems or loss of smaller populations through random events (Hogrefe *et al.* 2005, pp. 14–15).

Diseases, such as chytridiomycosis, which is caused by Bd, also could cause extirpation of these small populations. The SRM conservation plan gives a general idea of a large ''population'' in the viability criteria as 20 or more adult toads in a breeding ''locality'' (in this context ''locality'' is the same as a breeding population). Monitoring in Colorado and southeastern Wyoming in 2009 revealed that only 5 out of 47 breeding populations (11 percent), or 8 breeding sites out of 73 (about 9 percent), had more than 20 adults (CDOW 2010, entire). These statistics illustrate that very few populations in the SRM portion of the Eastern population are large. Consequently, we determine that the petition and information in our files present substantial scientific or commercial information indicating that isolation and small population size may be a threat to the Eastern population of the boreal toad.

Climate Change—Ray *et al.* (2008, p. 1) predict that Colorado will warm by about 1 °C (2.5 °F) by 2025 and by about 2 °C (4.0 °F) by 2050. Most of the observed snowpack loss in Colorado has occurred below 2,500 m (8,200 ft), with snowpack loss above this elevation predicted at between 10 and 20 percent (Ray *et al.* 2008, p. 2). With the range of the boreal toad largely above 2,500 m (8,200 ft) in the southern Rocky Mountains, it is likely that they will be shielded from extensive droughts. However, some drought effects were noted in boreal toads in the southern Rocky Mountains in 2002 during a drought cycle (Livo and Loeffler 2003, p. 11). Several breeding sites either remained dry throughout the breeding season or dried up prior to metamorphosis, reducing toad abundance. However, based on subsequent years with more precipitation, the 2002 drought may have been within normal variation and not related to climate change. Drought could exacerbate the decline of localized boreal toad populations, but is not considered a major factor in the widespread decline of the species.

There is a possibility that some diseases, such as chytridiomycosis, could expand their range into higher elevation boreal toad habitats if warmer temperatures occur due to climate change. However, references on this subject listed in the petition are not currently available to us and we have no information in our files to support this hypothesis. Warming temperatures could affect evaporative water loss from boreal toads, which could affect toad movement, breeding, and genetic interchange (Bartelt *et al.* 2010, p. 2675). Conversely, warmer temperatures could potentially help boreal toads by lengthening the growing season and increasing the rate of growth, leading to earlier metamorphosis and greater survival (Carey *et al.* 2005, p. 236). We find that the petition and information in our files does not present substantial scientific or commercial information indicating that climate change may be a threat to the Eastern population of the boreal toad.

Ultraviolet Radiation—The effect of increased UV–B radiation resulting from ozone depletion has been implicated as a contributing factor in amphibian declines, particularly on species inhabiting mountainous regions. However, studies are conflicting as to whether UV–B radiation has any effect on boreal toads and other frog species. A correlation was demonstrated between increased levels of UV–B and amphibian mortality in boreal toads and the Cascades frog (*Rana cascadae*), but there was no effect of ambient UV–B radiation on red-legged frog (*R. aurora*) hatching success (Blaustein *et al.* 1994, pp. 1791, 1793–1794). No evidence linking UV–B levels to the decline of the boreal toad was found in another study (Corn 1998, pp. 18, 21–25). Another study suggested that UV–B and pH could have synergistic effects on embryonic success (Long *et al.* 1995, entire). However, as stated in the ''Pollutants'' section under Factor A, pH does not appear to be an issue for boreal toads, and, consequently, the synergistic effects of UV–B and pH on boreal toads are not expected to occur in the wild. Therefore, we determine that the petition and information in our files do not present substantial scientific or commercial information indicating that UV–B radiation may be a threat to the Eastern population of the boreal toad.

Summary for Factor E

Based on our evaluation, the petition and information in our files present substantial information that listing the Eastern population of the boreal toad due to isolation and small population size may be warranted. Based on our evaluation, neither the petition nor information in our files presents substantial information that listing the Eastern population of the boreal toad due to climate change or UV–B radiation may be warranted. However, we will evaluate the potential threat of climate change and UV–B radiation more thoroughly during the 12-month status review if we determine that a valid DPS of boreal toad exists.

Finding

On the basis of our determination under section 4(b)(3)(A) of the Act, we determine that the petition presents substantial scientific or commercial information indicating that listing the Eastern population of the boreal toad as a DPS may be warranted. This finding is based on information provided under Factors C and E.

Because we have found that the petition presents substantial information indicating that listing the Eastern population of the boreal toad as a DPS may be warranted, we are initiating a status review to determine whether listing the Eastern population of the boreal toad under the Act is warranted. During the status review, we will fully address the cumulative effects of threats discussed under each factor. Additionally, if during the status review period the Eastern population of the boreal toad is classified as its own species, the Service will determine if listing the newly classified species is warranted.

The ''substantial information'' standard for a 90-day finding differs from the Act's ''best scientific and commercial data'' standard that applies to a status review to determine whether a petitioned action is warranted. A 90-day finding does not constitute a status review under the Act. In a 12-month finding, we will determine whether a petitioned action is warranted after we have completed a thorough status review of the species, which is conducted following a substantial 90-day finding. Because the Act's standards for 90-day and 12-month findings are different, as described above, a substantial 90-day finding does not mean that the 12-month finding will result in a warranted finding.

References Cited

A complete list of references cited is available on the Internet at *http://www.regulations.gov* and upon request from the Western Colorado Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Author

The primary authors of this notice are the staff members of the Colorado Field Office in Grand Junction and Lakewood, Colorado.

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 27, 2012.

Rowan W. Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2012–8806 Filed 4–11–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2010–0043; 4500030114]

RIN 1018–AV49

Endangered and Threatened Wildlife and Plants; Listing 23 Species on Oahu as Endangered and Designating Critical Habitat for 124 Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the comment period on our August 2, 2011, proposal to list as endangered and to designate critical habitat for 23 species on the island of Oahu in the Hawaiian Islands under the Endangered Species Act of 1973, as amended (Act); designate critical habitat for 2 plant species that are already listed as endangered; and to revise critical habitat for 99 plant species that are already listed as endangered or threatened. We also announce the availability of a draft economic analysis (DEA) of the proposed designation and an amended required determinations section of the proposal. We are reopening the comment period to allow all interested parties an opportunity to comment simultaneously on the proposed rule, the associated DEA, and the amended required determinations section. Comments previously submitted on this rulemaking do not need to be resubmitted, as they will be fully considered in preparation of the final rule. We are also considering revising the boundary for Oahu—Lowland Dry—Unit 8, from that described in the proposed rule, based on new information regarding the biological conditions within certain portions of the unit.

DATES: The comment period end date is May 14, 2012. We request that comments be submitted by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES:

Document Availability

You may obtain a copy of the DEA via *http://www.regulations.gov* at Docket No. FWS–R1–ES–2010–0043 or by contacting the office listed under **FOR FURTHER INFORMATION CONTACT**.

Comment Submission

You may submit comments by one of the following methods:

• *Electronically:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Search for Docket No. FWS–R1–ES–2010–0043, which is the docket number for this rulemaking.

• *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R1–ES–2010–0043; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Loyal Mehrhoff, Field Supervisor, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Box 50088, Honolulu, HI 96850; by telephone at 808–792–9400; or by facsimile at 808–792–9581. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information during this reopened comment period on our proposed listing of 23 species on Oahu and the designation of critical habitat for 124 species that was published in the **Federal Register** on August 2, 2011 (76 FR 46362), our DEA of the proposed designation, and the amended required determinations provided in this document. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act, including whether there are threats to the species from human activity, the degree to which threats from human activity can be expected to increase due to the designation, and whether that increase in threats outweighs the benefit of designation such that the designation of critical habitat may not be prudent.

(2) Specific information on:

(a) The amount and distribution of habitat for the 124 species described in the proposed rule;

(b) What areas that contain features essential to the conservation of the 124 species described in the proposed rule should be included in the designation, and why;

(c) The habitat components (primary constituent elements) essential to the conservation of the species, such as substrate, plant associations, stream characteristics, and the quantity and spatial arrangement of these features on the landscape needed to provide for the conservation of the species;

(d) What areas (if any) not occupied by the species are essential for the conservation of the species, and why; and

(e) Special management considerations or protections that the features essential to the conservation of the 124 species may require, including managing for the potential effects of climate change.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Any reasonably foreseeable economic, national security, or other relevant impacts that may result from designating any area that may be included in the final designation. We are particularly interested in any impacts on small entities, and the benefits of including or excluding areas from the proposed designation that are subject to these impacts.

(5) Information on whether the benefit of an exclusion of any particular area outweighs the benefit of inclusion under section 4(b)(2) of the Act, after considering both the potential impacts and benefits of the proposed critical habitat designation. Under section 4(b)(2) of the Act, we may exclude an area from critical habitat if we determine that the benefits of such exclusion outweigh the benefits of including that particular area as critical habitat, unless failure to designate that specific area as critical habitat will result in the extinction of the species.

(6) Information on the projected and reasonably likely impacts of climate change on the 124 species for which critical habitat is being proposed.

(7) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comment.

(8) Information on the extent to which the description of economic impacts in the DEA is reasonable and accurate.

(9) Information on the probable or reasonably foreseeable economic impacts to water users that could potentially result from the designation of critical habitat.

(10) Information on the potential cost of irrigation-related activities, as well as their timing and likely source of funding, Federal permit requirements, and the extent or scale of repairs or modifications required.

(11) Information on the planned development activities within the areas proposed as critical habitat.

(12) Information on primary constituent elements that may or may not be present in certain portions of proposed Oahu—Lowland Dry—Unit 8, as identified in Part II, Chapter 2 of the DEA (see Figure 3.3 of the DEA).

(13) Information on whether portions of proposed Oahu—Lowland Dry—Unit 8 are essential for the conservation of the species, as identified in Part II, Chapter 3 of the DEA.

(14) Information on potential future Federal actions and possible economic impacts of the proposed critical habitat designation within Oahu—Lowland Dry—Unit 8 at Kalaeloa, as identified in Part II, Chapter 3 of the DEA.

(15) Information on whether conservation measures or conservation recommendations that ensure Federal actions avoid jeopardizing the species are also adequate to avoid adversely modifying critical habitat.

If you submitted comments or information on the proposed rule during the initial comment period from August 2 to October 3, 2011 (76 FR 46362), please do not resubmit them. We will incorporate them into the public record as part of this comment period, and we will fully consider them in the preparation of our final determination. Our final determination concerning critical habitat will take into consideration all written comments and any additional information we receive during all comment periods. On the basis of public comments, we may, during the development of our final determination, find that areas proposed are not essential, are appropriate for exclusion under section 4(b)(2) of the Act, or are not appropriate for exclusion.

You may submit your comments and materials concerning the proposed rule or DEA by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. We will post all hardcopy comments on *http://www.regulations.gov* as well. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule and DEA, will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–R1–ES–2010–0043, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule and the DEA on the Internet at *http://www.regulations.gov* at Docket Number FWS–R1–ES–2010–0043, or by mail from the Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat for the 124 species described in the August 2, 2011, proposed rule (76 FR 46362). For more information on previous Federal actions for these species, refer to the proposed designation of critical habitat published in the **Federal Register** on August 2, 2011 (76 FR 46362).

Previous Federal Actions

On August 2, 2011, we published a proposed rule to list 23 species on Oahu as endangered and designate critical habitat for 124 species (76 FR 46362) over approximately 43,491 acres (ac) (17,603 hectares (ha)). Within that proposed rule, we announced a 60-day comment period, which closed October 3, 2011. Approximately 93 percent of the area proposed as critical habitat is already designated as critical habitat for other species, including 99 plant species for which critical habitat was designated in 2003 (68 FR 35950; June 17, 2003).

Critical Habitat

Section 3 of the Act defines critical habitat as the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection, and specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

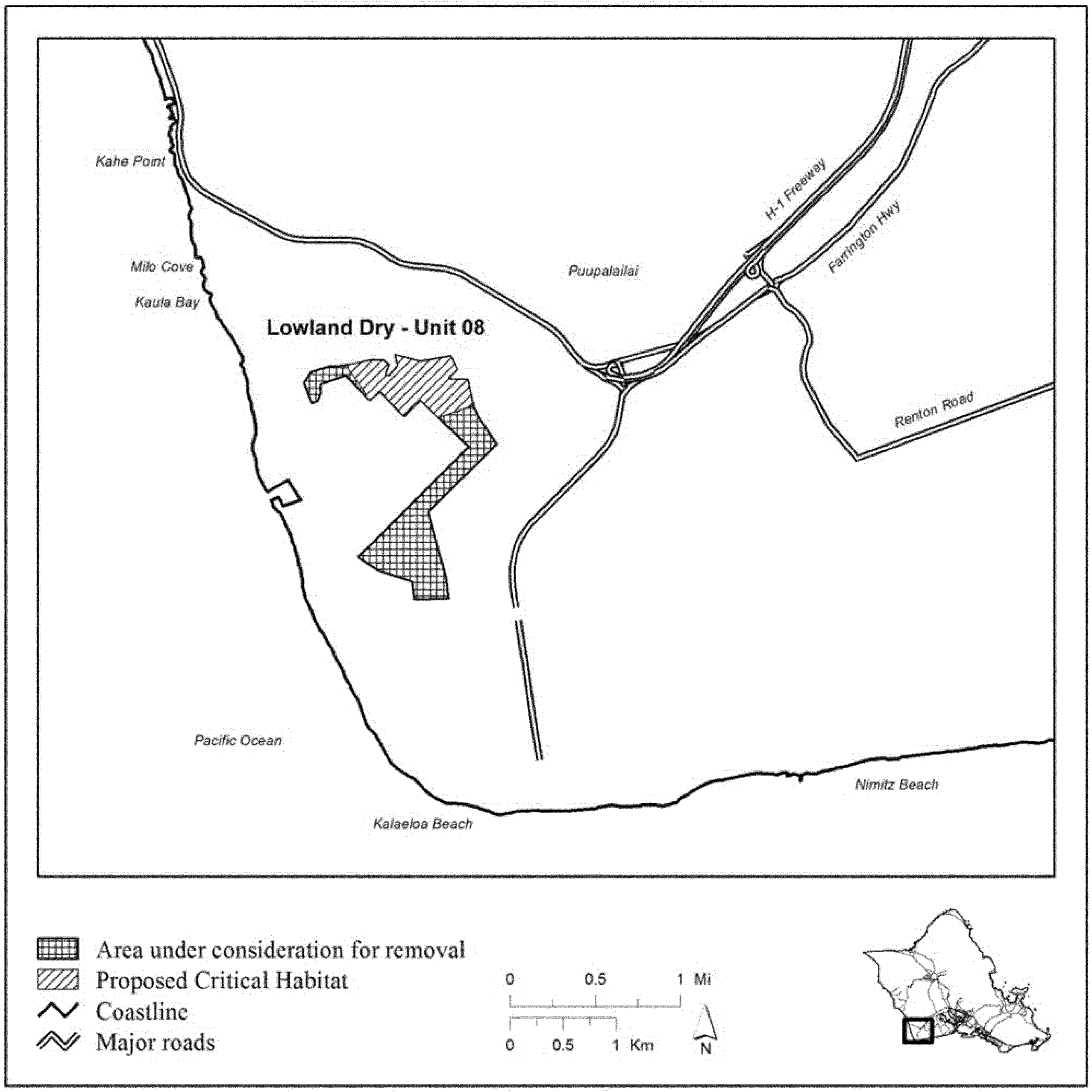
Potential Oahu—Lowland Dry—Unit 8 Boundary Adjustment

The August 2, 2011, proposed rule proposed to designate Oahu—Lowland Dry—Unit 8 as critical habitat for 17 endangered (or proposed endangered) plants (also see Part II, Chapter 3 of the DEA, pp. 61–64). This unit is composed of pockets of native and nonnative species. We initially determined this area to be essential for the conservation and recovery of these lowland dry plant species because we believed it provided the environmental conditions essential for each species, including the appropriate microclimatic conditions for germination and growth of the plants (e.g., light availability, soil nutrients, hydrologic regime, temperature, and space for population growth and expansion), as well as to maintain the historical geographical and ecological distribution of each species. In addition, proposed Oahu—Lowland Dry—Unit 8 provides the coral outcrop substrate that is a unique habitat requirement for *Chamaesyce skottsbergii* var. *skottsbergii.*

None of the endangered plants currently occur in Lowland Dry Unit 8, although both *Achyranthes splendens* var. *rotundata* and *Chamaesyce skottsbergii* var. *skottsbergii* were reported from this area as recently as 1989 and 1993, respectively. *Chamaesyce skottsbergii* var. skottsbergii is restricted to the arid coastal plain of Ewa, Oahu. It may have been a common species in the original ecosystem that existed on the Ewa Plains, although it is suspected to have been reduced to scattered remnants by the turn of the 20th century (FWS 1993, p. 6). In 1936, it was recorded as ''abundant'' in one location on the Ewa Plains but was not documented again for 40 years, when it was rediscovered in 1976, in the vicinity of the present Kalaeloa Barbers Point Deep Draft Harbor. In 1982, at the time of listing, this species was known from 4 occurrences containing approximately 1,000 to 1,500 individuals (Char and Balakrishnan 1979, p. 67; HBMP 2008). Almost all known individuals at that time were found in the area around Oahu—Lowland Dry—Unit 8. Surveys conducted between 1983 and 1984, in the vicinity of the former Barbers Point Naval Air Station, indicated there was a total of approximately 5,000 plants (HINHP 1991; USFWS 1993, pp. 13–15). However, surveys conducted a decade later located only several hundred plants in the same location (USFWS 1993, pp. 13–15). Currently *Chamaesyce skottsbergii* var. *skottsbergii* is only known from approximately 1,500 wild and outplanted individuals on the Navy's former Trap and Skeet Range and the Service's Kalaeloa Unit of the Oahu National Wildlife Refuge. This species has been extirpated from all other known locations on the Ewa Plains.

We are considering revising the boundaries of Oahu—Lowland Dry—Unit 8 based on comments received related to the physical and biological conditions of portions of the unit, and new biological information gained from field visits to Kalaeloa indicating certain portions of this unit may not be essential to the conservation of the species in question. During our field visits, we observed that approximately 69 percent of the originally proposed unit is no longer suitable due to development and land modification activities including grading, dredging, waste/recycle pile management, compost piles, solar array installation, fill deposition, golf course development, and road construction. Under section 3(5)(A)(ii) of the Act, specific areas outside the geographical area occupied by the species at the time it is listed in accordance with the provisions of section 4 of the Act can only be designated as critical habitat if such areas are essential for the conservation of the species. Those portions of Oahu—Lowland Dry—Unit 8 that may not be essential to the conservation of the species based on new biological information are identified below in Figure 1. We are considering removing approximately 185 ac (75 ha) from the proposed unit and designating critical habitat in the remaining approximately 107 ac (43 ha). Accordingly, we are seeking public comments regarding the removal from this unit of the areas that may not be essential for the conservation of the species.

Figure 1
Oahu–Lowland Dry Unit 8



Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act requires that we designate or revise critical habitat based upon the best scientific data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area as critical habitat, provided such exclusion will not result in the extinction of the species.

When considering the benefits of inclusion for an area, we consider the additional regulatory benefits that area would receive from the protection from adverse modification or destruction as a result of actions with a Federal nexus (activities conducted, funded, permitted, or authorized by Federal agencies), the educational benefits of mapping areas containing essential features that aid in the recovery of the listed species, and any benefits that may result from designation due to State or Federal laws that may apply to critical habitat.

When considering the benefits of exclusion, we consider, among other things, whether exclusion of a specific area is likely to result in conservation; the continuation, strengthening, or encouragement of partnerships; or implementation of a management plan. In the case of the 124 Oahu species identified in the proposed rule (76 FR 46362; August 2, 2011), the benefits of critical habitat include public awareness of the presence of the species and the importance of habitat protection, and, where a Federal nexus exists, increased habitat protection due to protection from adverse modification or destruction of critical habitat. In practice, situations with a Federal nexus exist primarily on Federal lands or for projects authorized, funded, or undertaken by Federal agencies.

Final decisions on whether to exclude any areas will be based on the best scientific data available at the time of the final designation, including information obtained during the comment period and information about the economic impact of designation. Accordingly, we have prepared a DEA concerning the proposed critical habitat designation, which is available for review and comment (see **ADDRESSES** section).

Draft Economic Analysis

This analysis draws heavily on economic analyses conducted for previous critical habitat designations, because there is a 93 percent overlap between the proposed designation and the prior critical habitat designations and because economic impacts, particularly to potential water resources, are similar between the proposed critical habitat and the previous designations. The DEA has been developed in two parts, because of differences in development potential based on the geographic area involved. Part I focuses on the proposed designation for 123 species on Oahu, exclusive of the Kalaeloa area. None of the proposed critical habitat units in this area contain significant residential, commercial, industrial, or agricultural development or operations, and few projects are anticipated within the proposed critical habitat units. This situation reflects that fact that most of the land is unsuitable for development, farming, or other economic activities due to the rugged mountain terrain, lack of access, remote locations, and existing land use controls that severely limit development and most other economic activities in the mountainous interior of Oahu. Part II of the DEA is focused on the City of Kapolei and the Kalaeloa area, which is west of the city of Honolulu, in the vicinity of the former Barbers Point Naval Air Station (NAS). The NAS was decommissioned in 1999, under the Base Realignment and Closure Act, and the surrounding community is in the process of developing a strategic plan for sustaining and developing the economy in this area. In May 2005, the Hawaii Community Development Authority, in response to the closure of the NAS, adopted a strategic plan that would develop Kalaeloa into a diversified economy. The City of Kapolei has also prepared an urban design plan that defines how they want to evolve as Kapolei develops into a secondary urban center to absorb future growth emanating from the City of Honolulu. The proposed critical habitat units overlap with some of the development envisioned for this area; this has been evaluated and fully considered in Part II of the DEA.

The DEA describes the economic impacts of all potential conservation efforts for these species; many of these costs will likely be incurred regardless of whether we designate critical habitat. The economic impact of the proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.'' The ''without critical habitat'' scenario represents the baseline for the analysis, considering protections already in place for the species (e.g., under the Federal listing and other Federal, State, and local regulations). The baseline, therefore, represents the costs incurred regardless of whether critical habitat is designated. The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts are those not expected to occur absent the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs; these are the costs we may consider in the final designation of critical habitat when evaluating the benefits of excluding particular areas under section 4(b)(2) of the Act.

Draft Economic Analysis, Part I

Because there is a 93-percent overlap between the critical habitat proposed on August 2, 2011, and the areas considered in the past economic analyses, and because of the similar nature of potential water resource economic impacts, this analysis draws heavily on previous economic analyses. Part I of the DEA was developed using relevant economic information from three detailed economic analyses prepared for previous proposed critical habitat rules on Oahu (Oahu elepaio, 66 FR 30372, June 6, 2001; 99 Oahu plants, 67 FR 37108, May 28, 2002; 12 picture-wing flies, 72 FR 67428, November 28, 2007). Part I of the DEA also considers relevant economic information from three economic analyses that evaluated potential impacts to water resources on other Hawaiian islands, which is an issue also being evaluated in this analysis (Newcomb's snail, 67 FR 15159, March 29, 2002; 83 Kauai and Niihau plants, 67 FR 36851, May 28, 2002; 48 species on Kauai, 73 FR 62592, October 21, 2008). Those studies present economic information and context regarding the regulatory and socio-economic baseline, against which the potential incremental impacts of the proposed designation are evaluated. For a further description of the methodology of the analysis in Part I of the DEA, see Chapter 3, ''Previous Economic Analyses of Critical Habitat Designations on Oahu.''

Part I of the DEA summarizes the previously predicted economic costs of critical habitat designation on 40,446 ac (16,371 ha) that overlap with the August 2, 2011, proposed critical habitat designation, and the areas that do not overlap. The terrestrial areas being proposed as critical habitat are remote and lack development potential. In addition, approximately 93 percent of the area proposed as critical habitat completely overlaps critical habitat that is already designated. Our previous economic analyses of critical habitat designations for the Oahu elepaio and 99 Oahu plants evaluated potential economic costs over a 10-year timeframe (2002–2012), and the previous economic analysis for the Hawaiian picture-wing fly species evaluated potential economic costs over a 20-year timeframe (2008–2028). We believe these analyses are still valid within the 93-percent-overlap area, as the potential activities and conservation measures considered in those studies are similar to those that would be applicable under the current proposal. We are aware of only a small number of section 7 consultations that have been conducted within the 93-percent-overlap area, because these areas lack development potential. In addition, the physical or biological features described within the overlap areas under the existing and proposed designations are similar (e.g., 99 Oahu plants (ecosystem type, elevation (68 FR 35950; June 17, 2003)); Oahu elepaio (ecosystem type, associated native species, rainfall, elevation (66 FR 63752; December 10, 2001)); Hawaiian picture-wing flies (ecosystem type, elevation, host plants (73 FR 73794; December 4, 2008))). Therefore, we anticipate few, if any incremental costs attributable to the proposed critical habitat designation in the 93-percent-overlap area beyond those identified in the previous economic analyses. We also do not anticipate section 7 consultation costs to be significantly different than those identified in our previous economic analyses within the 93-percent-overlap area. This is because: (1) Habitat is considered in section 7 consultations, regardless of critical habitat designation; (2) any conservation measures needed to protect a species' habitat requirements would be identified during section 7 consultation; (3) those measures would also conserve the physical or biological features that were identified for the existing and the proposed critical habitat designation; and (4) those measures would coincidentally benefit unoccupied critical habitat, as the occupied and unoccupied critical habitat areas entirely overlap.

Of the remaining 7 percent (2,478 ac (1,001 ha)) of proposed critical habitat that does not overlap existing critical habitat, 95 percent (2,354 ac (951 ha)) is classified as being in conservation districts, and 5 percent (124 ac (50 ha)) is within urban or agricultural districts. Figure 4 and the corresponding key in the draft economic analysis (pp. 23–25), identifies objectives for land uses within the conservation district zoning. However, 74 percent (92 ac (37 ha)) of these urban or agricultural district lands are within State forest reserves, parks, seabird sanctuaries, or natural area reserves, and are also unlikely to be developed. The remaining lands (32 ac (13 ha)) are on the Naval Radar Transmitting Facility at Lualualei (which are unlikely to be developed), or lands of unknown use. These unknown use lands are most likely roads and existing manmade structures, which do not contain the physical or biological features, or are not essential to the conservation of the species. Further, no section 7 consultations have been conducted in these areas to date. Accordingly, with the possible exception of presently unknown costs associated with the proposed damselfly critical habitat (as discussed in the next paragraph), we do not believe the proposed designation of critical habitat in the non-overlap areas would result in any appreciable economic impacts. This conclusion is based on the lack of development potential for these areas. We acknowledge there may be circumstances under which additional costs may be incurred because of the designation of critical habitat, for example, due to the nature of a particular project or because currently occupied habitat becomes unoccupied in the future. Accordingly, we are seeking information from the public on the potential costs of this critical habitat designation to ensure the final determination is based on the best available scientific and commercial information.

Our August 2, 2011, proposed rule includes the proposed listing of the blackline Hawaiian damselfly (*Megalagrion nigrohamatum nigrolineatum*), crimson Hawaiian damselfly (*Megalagrion leptodemas*), and oceanic Hawaiian damselfly (*Megalagrion oceanicum*) as endangered, and the proposed designation of critical habitat for these species. The aquatic life-history stages of these species may use open water areas, slow sections or pools, or stream riffle areas, and adults perch on streamside vegetation and patrol along stream corridors. For species like these damselflies, which are at risk because of loss of habitat, an action could jeopardize the continued existence of a listed species through alteration of its habitat, regardless of whether that habitat has been designated as critical habitat (51 FR 19927; June 3, 1986). Because Federal agencies would need to consider damselfly habitat impacts in occupied areas during section 7 consultation regardless of a critical habitat designation, any conservation measures needed to avoid jeopardy would, in most cases, be sufficient to avoid adversely modifying critical habitat (*i.e.,* the outcome of a section 7 consultation under the jeopardy standard and adverse modification standards would be similar). Accordingly, we do not anticipate the need for project modifications or measures to address effects to critical habitat beyond those that would result from the jeopardy analysis. We acknowledge there could be a difference between consulting on effects for some species and their critical habitat, depending on the particular circumstances of the Federal action being proposed. In addition, some level of incremental economic impact may accrue in unoccupied critical habitat areas, because they would not otherwise be subject to section 7 consultation. Critical habitat could also trigger incremental economic impacts if an occupied area were to become unoccupied as a result of a stochastic or other catastrophic event. In this situation, a Federal agency would still have a section 7 consultation responsibility based on the critical habitat designation, even though the species is no longer present. Conservation recommendations under this scenario could target management actions to reintroduce the species into the vacated critical habitat area. There have been few section 7 consultations in the areas being proposed as Hawaiian damselfly critical habitat, and we are generally unaware of any future development plans. In addition, there is very little information available on potential direct or indirect costs related to critical habitat designation in aquatic areas on Oahu or elsewhere in the Hawaiian Islands. Although future Federal actions that could affect either the damselflies or their critical habitat are unpredictable, the areas generally lack development potential because of their topography and remote locations.

Most of the damselflies' proposed primary constituent elements (PCEs) are related to elevation, annual precipitation, substrate, and associated native vegetation, which are comparable to those propsoed for the Oahu plant species identified in the proposed rule. However, the damselflies' proposed PCEs also have an aquatic habitat component (*e.g.,* slow reaches of streams, pools, etc.), which would be considered during section 7 consultation on a Federal action. Each of the units proposed as damselfly critical habitat is occupied by one or more of the damselfly species. Accordingly, it is likely that most, if not all, potential future section 7 consultation costs or project modifications costs would result from the listing of the damselflies, and would represent baseline costs. However, there is very little information available on potential direct or indirect costs related to critical habitat designation in aquatic areas on Oahu or elsewhere in the Hawaiian Islands. We acknowledge there could be circumstances under which additional costs may be incurred because of the designation of critical habitat, for example due to the nature of a particular project or because currently occupied habitat becomes unoccupied in the future. Because there is some uncertainty, we are seeking information from the public on the potential cost of activities involving water structures (including irrigation-related activities), their timing and likely source of funding, the extent or scale of future repairs or modifications contemplated, and Federal permits that may be required, to ensure the final determination is based on the best available scientific and commercial information. We will fully consider all comments we receive related to future water management activities, economic concerns, Federal involvement, or other regulatory requirements to ensure the final determination is based on the best scientific data available.

Draft Economic Analyis, Part II

Part II of the DEA assesses the potential economic impacts associated with the proposed 566-ac (229-ha) critical habitat designation at Kalaeloa, Oahu, for 24 plant species. Only two of these plants, *Achyranthes splendens* var. *rotundata* (round-leaved chaff flower) and *Chamaesyce skottsbergii* var. *skottsbergii* (Ewa Plains akoko) currently occur at Kalaeloa, although the other 22 species were historically present. Six of the seven proposed units are currently occupied by either *Achyranthes splendens* var. *rotundata* or *Chamaesyce skottsbergii* var. *skottsbergii,* and represent proposed unoccupied critical habitat for 22 other species. One proposed unit (Oahu—Lowland Dry—Unit 8) is not currently occupied by any of the 17 species for which this unit is being proposed as critical habitat. The critical habitat units that are occupied by the species are not expected to incur any appreciable economic impact related to additional conservation measures, because Federal actions in areas occupied by the species already undergo section 7 consultation, and the need to incorporate additional conservation measures related to critical habitat designation would generally not be anticipated. This is because the PCEs for occupied critical habitat areas are habitat-based (i.e., elevation, annual precipitation, substrate, canopy, subcanopy, and understory), and habitat is considered during section 7 consultations involving these species, regardless of a critical habitat (see Part II, Chapter 4 of the DEA). We acknowledge there could be a difference in conservation measures, depending on the particular circumstances of the Federal action being proposed, but we are unable to quantify that difference based on our consultation history to date (i.e., we have no section 7 precedent in Hawaii with which to formulate an incremental cost/value difference). In addition, because future Federal actions in these areas are unknown at this time, we are unable to reasonably predict their future impacts on the species and the proposed critical habitat areas. However, we are seeking comments on these issues.

Critical habitat could also trigger incremental economic impacts if an occupied area were to become unoccupied as a result of a stochastic or other catastrophic event. In this situation, a Federal agency would still have a section 7 consultation responsibility based on the critical habitat designation, even though the species is no longer present. Conservation recommendations under this scenario could target management actions to reintroduce the species into the vacated critical habitat area. However, we are unaware of any instances of this situation arising.

We received several comment letters in response to the proposed rule that published in the **Federal Register** on August 2, 2011 (76 FR 46362), expressing concern that the proposed critical habitat designation could result in economic impacts to current or planned activities, with particular emphasis directed toward the Oahu—Lowland Dry—Unit 8, near the Kalaeloa Barbers Point Deep Draft Harbor. Some of the economic activities that were specifically identified in this area included aggregate transshipment operations; hot mix asphalt plant facilities; harbor expansion; maritime and related service needs, including light industrial, warehouse, and distribution facilities; resort and mixed use residential/commercial activities; marina facilities; industrial lot development; biofuel tankfarm construction and transshipment operations; and solar power facilities. Other economic activities were identified in Oahu—Lowland Dry—Unit 10, where a solar power generating facility is planned. These comment letters are available for public review at *http://www.regulations.gov,* under docket number FWS–R1–ES–2010–0043.

Although these comments are informative from the standpoint of further understanding the ongoing and planned development activities in the area, absent a Federal nexus, the designation of critical habitat would have no direct economic impacts to those activities. We are also unaware of any indirect economic impacts that would result from critical habitat designation, absent a Federal nexus. Several of the commenters indicated they would provide additional comments related to economic impacts once the draft economic analysis for the proposed critical habitat designation became available for public review. In this regard, comments that specifically identify Federal permits, licenses, funding, or other Federal assistance that are or would be necessary for ongoing or planned development activities would be helpful. All comments received will be fully considered in the Service's final critical habitat determination.

In the absence of definitive data or other economic information, the analysis presents a range of economic effects. The lower-bound estimate of effects is that the landowners would incur no economic impact from the designation of critical habitat. The upper-bound estimate of effects is that each parcel owner would participate in section 7 consultation with the Service before initiating their action, and the Service, Federal action agency, and/or the parcel owner would incur additional costs (see DEA Table 4.3, p. 75).

Total incremental administrative costs to address critical habitat concerns in occupied critical habitat, in 2011 dollars over a 21-year timeframe, would be approximately $405 for technical assistances, $2,380 for an informal consultation, and $5,000 for a formal consultation. The potential upper-bound administrative costs to address critical habitat concerns for occupied critical habitat units assumes that every parcel within the unit would have a formal consultation because of critical habitat designation. The total annualized costs in 2011 dollars over a 21-year timeframe would be approximately $1,380 for the Service, $1,550 for the Federal action agency, $875 for the third (private or State) party receiving Federal funding or seeking a Federal permit, and $1,200 for the biological assessment.

Oahu—Lowland Dry—Unit 8 is the only unit that is not currently occupied by any of the 17 species for which it is proposed as critical habitat. Consequently, Federal agencies are not currently compelled to consult with the Service on any actions that they authorize, fund, or carry-out with regard to possible effects on the 17 plants for which critical habitat is proposed in this unit. In the future, should critical habitat be designated for this area, Federal agencies would need to consult with the Service to ensure that their actions do not adversely modify critical habitat. However, due to the infrequency of section 7 consultations with Federal agencies on private development activities, the Service is unsure how the designation of critical habitat will affect future conservation measures and associated economic impacts. This unit contains 13 separate parcels, none of which are owned by the Federal Government. Although the parcels in Oahu—Lowland Dry—Unit 8 are planned to be commercially developed, for the most part, it remains difficult for the Service to determine the likelihood that such planned activities will be subject to a consultation. The primary reason why the Service has difficulty predicting how the planned future activities will be subject to a section 7 consultation is the inability to identify a Federal nexus that would require consultation. Accordingly, we are seeking specific public comments in this regard.

Due to the uncertainty of whether or not future commercial development will be subject to a section 7 consultation, the analysis in Part II of the DEA presents a range of potential effects. The lower-bound estimate is no economic effect because future development would not be subject to a section 7 consultation. However, should future development require section 7 consultation, it would presumably be attributable to the proposed critical habitat designation. The upper-bound estimate of effects is that each parcel owner would participate in section 7 consultation with the Service before initiating their action, and the Service, Federal action agency, or the parcel owner would incur additional administrative costs. The upper-bound estimate of administrative costs to address critical habitat concerns for a single parcel in unoccupied critical habitat, annualized in 2011 dollars over a 21-year timeframe, would be approximately $5,500 for the Service, $6,200 for the Federal action agency, $3,500 for the third (private or State) party receiving Federal funding or seeking a Federal permit, and $4,800 for the biological assessment, or $20,000 total annualized costs.

With regard to possible costs for conservation measures, as discussed above, the Service cannot identify a reasonably foreseeable Federal nexus which would lead to a formal section 7 consultation, related to the types of future uses identified in the Kapolei Area Long Range Master Plan or the Kalaeloa Master Plan. Therefore, the analysis estimates the upper-bound limit of such economic impacts based on land assessments and the percentage of parcel lands proposed as critical habitat. Specifically, because the Service is unable to estimate how much of the proposed critical habitat could be disturbed as part of planned future development activities without violating the prohibition on destroying or adversely modifying critical habitat, this analysis bases its upper-bound estimate of economic impacts using the very conservative approach that the designation could effectively lead to all of the proposed areas remaining in an open, undeveloped state. Oahu—Lowland Dry—Unit 8 surrounds the Kalaeloa Barbers Point Deep Draft Harbor. This unit consists of 13 mostly undeveloped distinct parcels ranging from as little as 3 ac (1.2 ha) to over 400 ac (162 ha) in size. The Kapolei Area Long Range Master Plan generally identifies intense development for these parcels, and the County has already zoned these areas in a manner appropriate for planned future development. The total current assessment for these parcels is slightly over $206 million, which according to the Real Property Assessment Division, reflects the current market value for the properties. The analysis assumes that the designation of critical habitat could lead to a loss in land values if property owners are unable to implement their development plans. The upper-bound annualized property value impacts from critical habitat designation over a 21-year timeframe is a total of $55,806,934 for all 13 parcels in proposed Oahu—Lowland Dry—Unit 8. Since the DEA was prepared before the Service gained new biological information on the unit, the approximate $55.8 million estimate is based on the 292 acres originally proposed within the unit. As discussed above, we are considering removing 185 acres (approximately 63%) of the area originally proposed as critical habitat from this unit. A proportional adjustment to the $55.8 million upper-bound estimate would result in an estimated $20.6 million in economic costs for the 107 acres remaining in the unit, under the worst-case scenario (*i.e.,* no development may occur). However, this scenario is unlikely, and actual costs will probably be much less.

Given the relatively small land area proposed for designation island-wide, coupled with the fact that the designation is generally not expected to result in any additional conservation measures for the species above and beyond the baseline (particularly in occupied critical habitat areas), this designation is not expected to significantly affect land market prices on the island even though the designation could have an effect on individual parcels. The designation of critical habitat could lead to economic costs if the designation caused either significant delays in the planned development of the land or if the designation leads to restrictions in the type of development allowed. In the first instance, a delay in planned development, which could be caused by a section 7 consultation with the Service that otherwise would not have occurred absent critical habitat, may correspond to a delay in the realization of revenue streams associated with the development (i.e., rental income) even if the consultation results in no change to the type of development initially planned. Land value losses could be greater under the second scenario if a section 7 consultation results in a change in the type of development that would have occurred absent a designation of critical habitat and associated consultation with the Service. For example, if a section 7 consultation results in less land area being developed than originally conceived and allowed under pre-existing conditions, the total value of the development and associated revenue streams may be less.

There could also be a difference between consulting on effects for some species and their critical habitat, depending on the particular circumstances of the Federal action being proposed. Some level of incremental economic impact to land values may accrue in unoccupied critical habitat areas, because they would not otherwise be subject to section 7 consultation. Critical habitat could also trigger incremental economic impacts if an occupied area were to become unoccupied as a result of a stochastic or other catastrophic event. In this situation, a Federal agency would still have a section 7 consultation responsibility based on the critical habitat designation, even though the species is no longer present. Conservation recommendations under this scenario could target management actions to reintroduce the species into the vacated critical habitat area. We are unaware of any instances of this situation arising, although there could potentially be an impact to land values if a Federal action were to be proposed in such areas.

As we stated earlier, we are soliciting data and comments from the public on the DEA, as well as all aspects of the proposed rule and our amended required determinations. We may revise the proposed rule or supporting documents to incorporate or address information we receive during the public comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of the species.

Required Determinations—Amended

In our August 2, 2011, proposed rule (76 FR 46362), we indicated that we would defer our determination of compliance with several statutes and executive orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have now made use of the DEA data to make these determinations. In this document, we affirm the information in our proposed rule concerning Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 12630 (Takings), E.O.

13132 (Federalism), E.O. 12988 (Civil Justice Reform), E.O. 13211 (Energy, Supply, Distribution, and Use), E.O. 13175 (Government-to-Government Relationship with Tribes), the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), and the National Environmental Policy Act (42 U.S.C. 4321 *et seq*). However, based on the DEA data, we are amending our required determination concerning the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 802(2)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed designation, we provide our analysis for determining whether the proposed rule would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revise this determination as part of our final rulemaking.

According to the Small Business Administration, small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ‘‘significant economic impact’’ is meant to apply to a typical small business firm's business operations.

To determine if the proposed designation of critical habitat for the 124 species included in the proposed rule (76 FR 46362, August 2, 2011) would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities, such as commercial and residential development. In order to determine whether it is appropriate for our agency to certify that this rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement. Critical habitat designation will not affect activities that do not have any Federal involvement; designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In areas where listed species are present, including the 101 Oahu plant species described in the proposed rule, Federal agencies already are required to consult with us under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would, in most cases, be incorporated into the existing consultation process.

Our regulatory flexibility analysis considers the potential economic effects on small entities resulting from the implementation of conservation actions related to the proposed designation of critical habitat for 124 Oahu species, and looks in more detail at the proposed designation in the Kalaeola area (which is considered in Part II of the DEA), based on the potential for development in that area. As estimated in Part I, Chapter 11 of the DEA, incremental impacts of the proposed designation in Oahu with the exception of Kalaeloa would likely be limited to additional incremental costs of time spent by the Service, Federal action agency, and any third parties in section 7 consultation over and above time spent on the jeopardy analysis component of the consultation. We anticipate few, if any, incremental costs attributable to the proposed critical habitat designation where it overlaps existing critical habitat (approximately 93-percent overlap). Within this area, any conservation measures needed to protect the physical or biological features in occupied habitat areas would likely be identified during section 7 consultation based on occupancy by the species. Those measures would coincidentally benefit unoccupied habitat because those areas entirely overlap. Ninty-five percent of the non-overlap areas is classified as conservation district, and 5 percent is within urban or agricultural districts. However, 74 percent of the lands within urban or agricultural districts are within State forest reserves, parks, seabird sanctuaries, or natural area reserves, and are unlikely to be developed. Most of the remaining lands are on the Naval Radar Transmitting Facility at Lualualei (which are unlikely to be developed) or lands of unknown use (most likely roads and existing manmade structures).

Small entities may participate in section 7 consultation as a third party (the primary consulting parties being the Service and the Federal action agency); therefore, it is possible that the small entities may spend additional time considering critical habitat during section 7 consultation for the 124 Oahu species. Based on the best available information, these administrative impacts would likely be the only potential incremental impacts of critical habitat that may be borne by small entities. We do not believe the proposed designation would have a significant effect on a substantial number of small entities because none of the proposed critical habitat units contains significant residential, commercial, industrial, or agricultural development or operations, and few projects are anticipated within the proposed critical habitat. Any existing and planned projects, land uses, and activities that could affect the proposed critical habitat that have no Federal involvement would not require section 7 consultation and would not be restricted by the requirements of the Act. Finally, many of the anticipated projects and activities with Federal involvement are conservation efforts that would be expected to trigger formal section 7 consultations. If formal consultation were to be required, we anticipate that a project proponent could modify the project or take measures to protect the affected species or critical habitat, such as establishing conservation set-asides, management of competing nonnative species, restoration of degraded habitat, and regular monitoring. The Service has been involved with these types of projects for many years throughout the Hawaiian Islands. We are unaware of instances where these types of activities have resulted in any significant economic impacts to the individuals or agencies involved.

In addition, in the 2001, 2003, and 2008 economic analyses for the designation of critical habitat for the Oahu elepaio, 99 species of Oahu plants, and 12 Hawaiian picture-wing flies, respectively, we evaluated the potential economic effects on small entities resulting from the protection of these species and their habitats related to the proposed designation of critical habitat, and determined that designation would not have a significant economic impact on a substantial number of small entities. The significant overlap (93 percent) between the critical habitat designations for the Oahu elepaio, 99 Oahu plant species, and 6 Oahu picture-wing flies and this proposed critical habitat designation is further evidence that the designation of critical habitat in the areas evaluated in Part I of the DEA will not have a significant economic impact on a substantial number of small entities. None of the proposed critical habitat units considered in Part I of the economic analysis contains significant residential, commercial, industrial, or agricultural development or operations, and few projects are anticipated within the proposed critical habitat. This situation reflects the fact that most of the land is unsuitable for development, farming, or other economic activities due to the rugged mountain terrain, lack of access, and remote locations, and existing land-use controls severely limit development and most other economic activities in the mountainous interior of Oahu.

Although some existing and continuing activities involve the operation and maintenance of existing manmade features and structures in certain areas, these areas do not contain the primary constituent elements for the species, and would not be impacted by the designation. Any existing and planned projects, land uses, and activities that could affect the proposed critical habitat that have no Federal involvement would not require section 7 consultation and would not be restricted by the requirements of the Act. Finally, many of the anticipated projects and activities with Federal involvement are conservation efforts that would be expected to trigger formal section 7 consultations. If formal consultation were to be required, we anticipate that a project proponent could modify the project or take measures to protect the affected species or critical habitat, such as establishing conservation set-asides, management of competing nonnative species, restoration of degraded habitat, and regular monitoring. The Service has been involved with these types of projects for many years throughout the Hawaiian Islands. We are unaware of instances where these types of activities have resulted in any significant economic impacts to the individuals or agencies involved.

Our regulatory flexibility analysis for the Kalaeloa area contained in Part II of the DEA is based on an assessment of the highest level of incremental costs (upper-bound) of critical habitat designation due to reductions in land value due to development restrictions following the designation of critical habitat and administrative consultation costs. The analysis focuses on impacts to development activities, which may be experienced by small entities, and assumes that the designation of critical habitat would primarily impact businesses in the building construction industry. As estimated in Chapter 4 of Part II the DEA, incremental impacts of the proposed designation in occupied habitat areas would likely be limited to additional incremental costs of time spent by the Service, Federal action agency, and any third parties in section 7 consultations over and above the time spent on the jeopardy analysis component of the consultation. Small entities may participate in a section 7 consultation as a third party, and it is possible that they could spend additional time considering critical habitat during section 7 consultation for these 24 plant species. These administrative impacts would likely be the only potential incremental impacts of designating critical habitat in occupied habitat that may be borne by small entities. Critical habitat could theoretically trigger incremental economic impacts if an occupied area were to become unoccupied as a result of a stochastic or other catastrophic event. In this situation, a Federal agency would still have a section 7 consultation responsibility based on the critical habitat designation, even though the species is no longer present. Conservation recommendations under this scenario could target management actions to reintroduce the species into the vacated critical habitat area. However, we are unaware of any actual instances of this situation arising.

Based on the DEA, the only critical habitat unit facing potential property value impacts would be the unoccupied unit, Oahu—Lowland Dry—Unit 8. Property value impacts were used because we are not certain about how the designation will affect future conservation measures through the section 7 consultation process, so we used a ''worst case scenario'' assumption that designation could effectively lead to critical habitat remaining in an undeveloped state. However, we believe this is extremely unlikely to occur. Oahu—Lowland Dry—Unit 8 is the only proposed critical habitat unit in Kalaeloa that is not currently occupied by at least one listed species, and consequently, Federal agencies are not currently compelled to consult with the Service on actions they authorize, fund, or carry out in this unit. Although some of the parcels in Oahu—Lowland Dry—Unit 8 are planned to be commercially developed, it is difficult to determine the likelihood that planned activities would have Federal involvement, which would trigger the need for section 7 consultation. Due to this uncertainty, the DEA presents a range of possible effects. The lower-bound estimate is that there would be no economic effect because future development would not be subject to section 7 consultation. As Oahu—Lowland Dry—Unit 8 is unoccupied, any costs associated with section 7 consultation would be attributable to the proposed critical habitat designation. The upper-bound estimate assumes none of the parcels in Oahu—Lowland Dry—Unit 8 could be developed, which could lead to a property value loss. If this were to occur, potentially up to 13 small developers could be affected with an average financial impact of 2.0 percent to 2.8 percent to their annual receipts. Similarly, under the upper-bound assumption that every parcel would incur a formal consultation, the financial impact (due to administrative costs) to the average small developer would be 0.03 percent of annual receipts. Under this scenario, up to 34 small businesses could potentially be impacted, although it is unlikely that every parcel would be subject to section 7 consultation in the future. It is also unlikely that every potentially affected developer would be a small business as defined by the Small Business Administration. Accordingly, the potential economic impacts of the proposed designation on small entities are likely overstated. There is also no factual basis for the Service to conclude the designation of critical habitat would result in the inability of landowners to develop their parcels in the Kalaeloa area, based on our existing section 7 consultation history for this area.

In summary, we have considered whether the proposed designation of critical habitat for 124 species on Oahu would result in a significant economic impact on a substantial number of small entities. Information for our analysis was gathered from the Small Business Administration, stakeholders, and the

Service. For the above reasons and based on currently available information, we certify that if promulgated, the proposed designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Authors

The primary authors of this notice are the staff members of the Pacific Islands Fish and Wildlife Office, Pacific Region, U.S. Fish and Wildlife Service.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 30, 2012.

Rachel Jacobson,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2012–8807 Filed 4–11–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 110202088–2183–01]

RIN 0648–BA34

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Bottlenose Dolphin Take Reduction Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: The National Marine Fisheries Service (NMFS) proposes to amend the Bottlenose Dolphin Take Reduction Plan (BDTRP) and implementing regulations by permanently continuing medium mesh gillnet fishing restrictions in North Carolina coastal state waters, which would otherwise expire on May 26, 2012. This action will remove the expiration date to continue current nighttime fishing restrictions of medium mesh gillnets operating in North Carolina coastal state waters from November 1 through April 30. Members of the Bottlenose Dolphin Take Reduction Team (BDTRT) recommended these regulations be continued permanently, without modification, to ensure: (1) Continued conservation of strategic bottlenose dolphin stocks in North Carolina with historically high serious injury and mortality rates associated with medium mesh gillnets; and (2) BDTRP goals are met. NMFS also proposes to amend the BDTRP with updates, including updates recommended by the BDTRT for non-regulatory conservation measures.

DATES: Written comments on the proposed rule must be received no later 5 p.m. eastern time on May 14, 2012.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2010–0230, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*. To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter NOAA–NMFS–2010–0230 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- *Mail:* Submit written comments to Assistant Regional Administrator for Protected Resources, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701–5505.
- *Fax:* 727–824–5309; Attn: Assistant Regional Administrator for Protected Resources.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

This proposed rule, the BDTRP, 2008 BDTRP amendment, BDTRT meeting summaries with consensus recommendations, and other background documents are available at the Take Reduction Team web site: *http://www.nmfs.noaa.gov/pr/interactions/trt/bdtrp.htm,* or by submitting a request to Stacey Horstman [see **FOR FURTHER INFORMATION CONTACT**].

FOR FURTHER INFORMATION CONTACT: Stacey Horstman, NMFS Southeast Region, *Stacey.Horstman@noaa.gov,* 727–824–5312; or Kristy Long, NMFS Office of Protected Resources, *Kristy.Long@noaa.gov,* 301–427–8402.

SUPPLEMENTARY INFORMATION:

Regulatory Changes to the BDTRP

BDTRP and Medium Mesh Gillnet Restrictions

Section 118(f)(1) of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1387(f)(1)) requires NMFS to develop and implement take reduction plans to assist in the recovery or prevent the depletion of strategic marine mammal stocks that interact with Category I and II fisheries. The MMPA includes in its definition of ''strategic stock'' a marine mammal stock: (1) For which the level of direct human-caused mortality exceeds the potential biological removal (PBR) level; (2) which is declining and likely to be listed as a threatened species under the Endangered Species Act (ESA); or (3) which is designated as a depleted species under the MMPA (16 U.S.C. 1362(1), (19), and (20)). PBR is the maximum number of animals, not including natural mortalities, that can be removed annually from a stock, while allowing that stock to reach or maintain its optimum sustainable population level. Category I or II fisheries are fisheries with frequent or occasional incidental mortality and serious injury of marine mammals, respectively (16 U.S.C. 1387(c)(1)(A)(i) and (ii)).

As specified in the MMPA, the short-term goal of a take reduction plan is to reduce, within six months of its implementation, the incidental mortality or serious injury of marine mammals taken in the course of commercial fishing operations to levels less than PBR for the stock (16 U.S.C. 1387(f)(2)). The long-term goal of a plan is to reduce, within 5 years of its implementation, the incidental mortality or serious injury of marine mammals taken in the course of commercial fishing operations to insignificant levels approaching a zero mortality and serious injury rate, taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans. The MMPA also requires NMFS to amend take reduction plans and implementing regulations as necessary to meet the requirements of this section.

On April 26, 2006, NMFS published a final rule (71 FR 24776) implementing the BDTRP, with a May 26, 2006, effective date. The BDTRP contains both regulatory and non-regulatory conservation measures to reduce serious injury and mortality of 13 strategic stocks of bottlenose dolphins (*Tursiops truncatus*) (previously considered one coastal migratory stock; see section on *Revisions to the Western North Atlantic Coastal Bottlenose Dolphin Stock*) in Category I and II commercial fisheries operating within the stocks' distributional range. Both the regulatory and non-regulatory conservation measures are designed to meet the BDTRP's short-term goal and provide a framework for meeting the long-term goal. The regulatory measures in the BDTRP include seasonal gillnet restrictions, gear proximity requirements, and gear length restrictions. The non-regulatory measures include continued research and monitoring, enforcement of regulations, outreach, and collaborative efforts.

The specific regulatory measures addressed in this proposed rule that would otherwise expire on May 26, 2012, are fishing prohibitions on nighttime medium mesh gillnets in North Carolina coastal state waters from November 1 through April 30, annually. Medium mesh gillnets are defined in the BDTRP as greater than 5-inch (12.7 cm) to less than 7-inch (17.8 cm) stretched mesh. The intent of the prohibitions is to reduce bottlenose dolphin serious injuries and mortalities by reducing gillnet soak times associated with medium mesh gillnets targeting spiny dogfish (*Squalus acanthias*) in North Carolina coastal state waters. During the winter (November 1 through April 30), four strategic bottlenose dolphin stocks (two coastal and two bay, sound, and estuary) occur in North Carolina state waters at various times. The prohibitions were implemented in North Carolina coastal state waters because bottlenose dolphin mortalities were observed from 1995 to 2000 in these waters during the winter. These mortalities were associated with medium mesh gillnets targeting spiny dogfish with long, overnight soak durations.

When the BDTRT originally deliberated on their consensus recommendations for a draft BDTRP in 2002 and 2003, they recognized the inadvertent benefit of recently implemented spiny dogfish fishery management plans (FMPs) in reducing serious injury and mortality of bottlenose dolphins by virtually eliminating spiny dogfish fishing effort in North Carolina. However, the BDTRT also recognized the dynamic nature of the spiny dogfish fishery, which is managed by both state and Federal entities. The uncertainty about on-going management of the fishery resulted in a process that was dynamic and unreliable for bottlenose dolphin conservation. Therefore, the BDTRT recommended the nighttime medium mesh prohibitions be included in the BDTRP with an expiration date to ensure regular review of the spiny dogfish fishery and management.

The nighttime medium mesh gillnet restrictions were originally implemented in the BDTRP on May 26, 2006, with an expiration date of May 26, 2009. The BDTRT subsequently recommended extending the restrictions for an additional three years to ensure continued bottlenose dolphin conservation benefits and evaluate the need for permanent restrictions due to recent changes to the spiny dogfish population status and continued uncertainty in fishery management. On December 19, 2008, NMFS published a final rule (73 FR 77531) amending the BDTRP by extending the measures' expiration date until May 26, 2012. The BDTRT met on September 9–11, 2009, and recommended NMFS make the restrictions permanent because of continued spiny dogfish FMP changes, as the spiny dogfish fishery was no longer considered overfished, and fishing effort increased for spiny dogfish in North Carolina. Removing the expiration date, thereby permanently maintaining the existing restrictions, ensures continued bottlenose dolphin conservation benefits from reduced soak durations of medium mesh gillnets in North Carolina coastal state waters.

Medium Mesh Gillnets in North Carolina and Spiny Dogfish FMPs

Medium mesh gillnets fished in coastal state waters of North Carolina fall under the mid-Atlantic gillnet fishery. The mid-Atlantic gillnet fishery is classified on the MMPA List of Fisheries as a Category I fishery, which is defined as a fishery that has frequent incidental mortality and serious injury of marine mammals (i.e., greater than 50 percent of a stock's PBR level). In North Carolina, medium mesh gillnets are typically used to target spiny and smooth dogfish, king mackerel, flounder, and other shark species, with spiny dogfish as the primary target species (Rossman and Palka 2004).

Spiny dogfish are managed from Maine to North Carolina by two Federal Fishery Management Councils in Federal waters and an interstate fishery management commission in state waters. NMFS listed spiny dogfish as overfished in 1998 (63 FR 17820, April 10, 1998). In January 2000, NMFS implemented a Federal FMP (65 FR 1557) to conserve spiny dogfish in Federal waters. Among other things, the FMP implemented a coastwide commercial quota that is specified annually and split into two seasonal fishing periods (Period 1: May 1 to October 31; Period 2: November 1 to April 30). Each fishing period has separate possession trip limits, specified annually, to allow for spiny dogfish bycatch to be sold while managing catch rates (63 FR 17820, April 10, 1998; ASMFC 2007).

The Atlantic States Marine Fisheries Commission (ASMFC) issued an emergency action in 2000 requiring states to mirror Federal closures in state waters. An Interstate FMP was developed in November 2002 to manage spiny dogfish fishing in state waters and implemented in the 2003/2004 fishing year. The Interstate FMP largely mirrors the Federal FMP, setting annual commercial quotas and separate possession limits to help manage spiny dogfish catch rates for the same two fishing periods (ASMFC 2007). All commercial landings count toward the Interstate FMP quota regardless of where the fish are caught (i.e., state or Federal waters) (ASMFC 2002).

Annually, NMFS reviews the Federal FMP and ASMFC reviews the Interstate FMP, based on the most recent estimate of spiny dogfish fishing mortality and spawning stock biomass. The 2006 estimate of fishing mortality for spiny dogfish indicated the population was not overfished and overfishing was not occurring (NMFS 2006). In 2010, the spiny dogfish stock was declared rebuilt based on 2009 spawning stock biomass estimates exceeding biomass targets since 2008 (75 FR 36012, June 24, 2010; Rago and Sosebee 2010). Both state and Federal annual commercial coastwide quotas and possession limits have increased in accordance with changes in the spiny dogfish stock status (see Table 1).

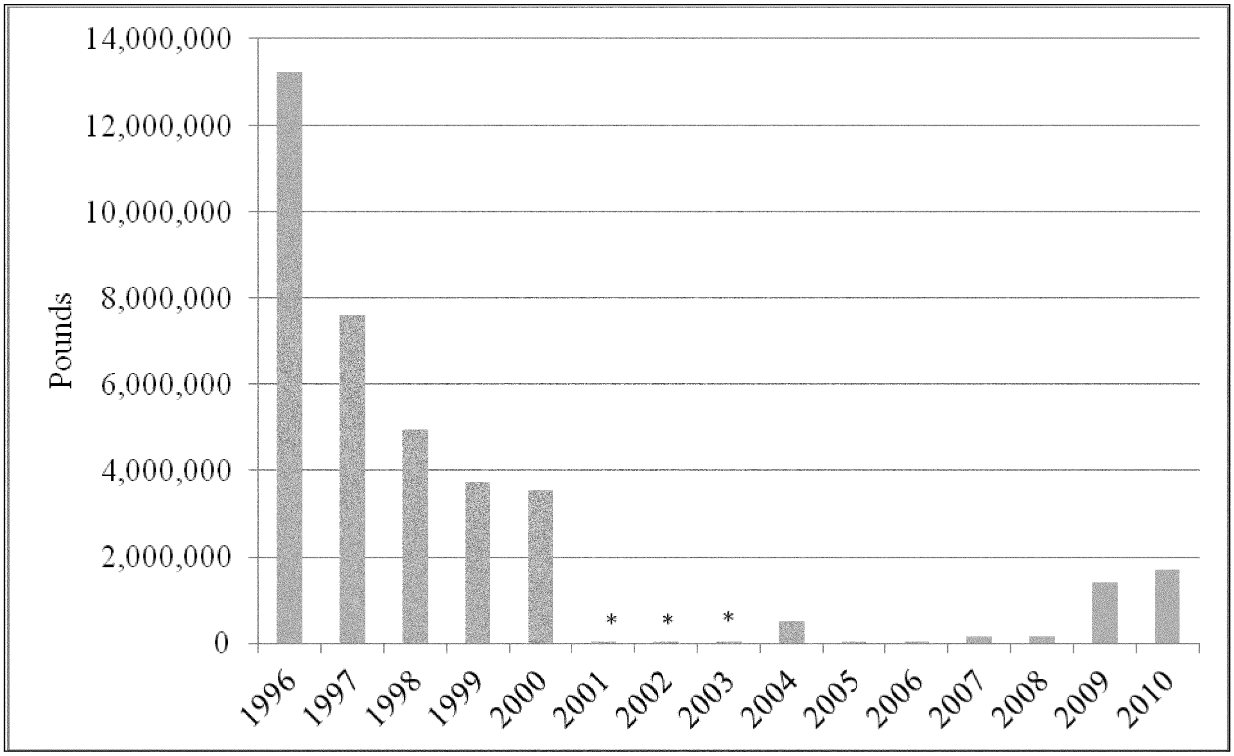
TABLE 1—STATE AND FEDERAL FMP QUOTAS AND POSSESSION LIMITS SINCE 2006

Fishing year	State (ASFMC)		Federal (NMFS)	
	Coastwide quota (million pounds)	Possession limit (pounds)	Coastwide quota (million pounds)	Possession limit (pounds)
2006/2007	6	States determine	4	600
2007/2008	6	3,000	4	600
2008/2009	8	3,000	4	600
2009/2010	12	3,000	12	3,000
2010/2011	15	3,000	15	3,000
2011/2012	20	3,000	20	3,000

The implementation of the FMPs and quota changes has affected spiny dogfish effort and landings in North Carolina since 2001 (see Figure 1). Targeting spiny dogfish in North Carolina was virtually eliminated following implementation of the FMPs, as evidenced by low spiny dogfish landings. Spiny dogfish landings in North Carolina averaged 6,609,821 pounds from 1996 to 2000 prior to the implementation of the FMPs (NMFS, Fisheries Statistic Division, pers. comm. and ASMFC 2011a). From 2001 to 2006, after implementation of the FMPs and before the spiny dogfish population was considered no longer overfished, landings in North Carolina averaged 92,243 pounds (NMFS, Fisheries Statistic Division, pers. comm. and ASMFC 2011a). Despite the increasing state quotas and possession limits through the 2008 fishing year, spiny dogfish landings in North Carolina remained comparatively low for the 2007–2008 fishing years, averaging 154,135 pounds (NMFS, Fisheries Statistic Division, pers. comm. and ASMFC 2011a).

Two major factors contributed to preventing greater increases in landings of spiny dogfish in North Carolina. First, the decreased landings of spiny dogfish in North Carolina following implementation of the FMPs were mostly due to the seasonal specifications of commercial quotas. The FMPs' commercial quotas, established annually and split semi-annually, were based on the north-south spiny dogfish migration to help maintain the seasonal and geographic distribution of landings among states. Because of the species' annual migratory pattern along the United State's east coast, quota overages often occurred in the northern states associated with harvest Period 1, resulting in reduced or restricted harvest for southern states in Period 2 (ASMFC 2002). For example, historic peak harvest for spiny dogfish in North Carolina state waters occurred during February and March, corresponding to harvest Period 2. The state and Federal quotas were often already met before harvest Period 2 because spiny dogfish remain off the coasts of the northern states until winter (ASMFC 2008). Therefore, the seasonal specifications of the FMP quotas based on the spiny dogfish migration allowed northern states to intercept spiny dogfish and meet FMP quotas before their seasonal migration south to North Carolina (NCDMF 2008). Second, following the implementation of the FMPs, the mid-Atlantic processors closed, leaving only two processors in New England (ASMFC 2002). The processing plants are at times saturated with spiny dogfish harvested from states north of North Carolina, leaving little to no market to harvest and process the fish when they arrive in North Carolina. Furthermore, in a predominantly bycatch fishery with possession limits at 600 or even 3,000 pounds, it was not cost effective for fishermen or dealers in North Carolina to truck spiny dogfish to the processors in New England given the high fuel costs and small amounts of fish allowed for harvest.

FIGURE 1. SPINY DOGFISH LANDINGS IN NORTH CAROLINA FROM 1996 THROUGH 2010 (NMFS, FISHERIES STATISTIC DIVISION, PERS. COMM. AND ASMFC 2011A)



*Landings not reported for confidentiality purposes, as landings were from less than three participants.

Because the semi-annual quota was not maintaining the historical distribution of landings or allowing for consistent quota allocation for southern states, ASMFC approved Addendum II and III to the Interstate FMP in October 2008 and April 2011, respectively. Addendum II was issued retroactively for the 2008/2009 fishing year, establishing regional quotas replacing the overall seasonal allocation. The quota was redistributed at 58% for the Northern Region (Maine, New Hampshire, Massachusetts, Rhode Island, and Connecticut); 26% for the Southern Region (New York, New Jersey, Delaware, Maryland, and Virginia); and 16% for North Carolina. If the quota was exceeded in a region or North Carolina, the amount exceeding the allocation was deducted from the corresponding region or North Carolina for the next fishing season. North Carolina was specifically allocated a percentage of the quota to ensure available quota when the fish arrive in North Carolina waters (ASMFC 2008). Following Addendum II, average landings for spiny dogfish in North Carolina from 2009–2010 increased to 1,562,400 pounds (NMFS, Fisheries Statistic Division, pers. comm. and ASMFC 2011a).

Addendum II addressed the inability of North Carolina to harvest spiny dogfish, but it did not allow the Southern Region to adjust possession limits based on market demand. Addendum III to the interstate FMP was, therefore, approved for the 2011/2012 fishing year, providing state-specific allocation for all states in the Southern Region and allowing individual states greater control of spiny dogfish fishing effort (ASMFC 2011b). Among other things, Addendum III divided the Southern Region annual quota of 42% into state-specific shares, including a share of 14.036% to North Carolina. Therefore, North Carolina had a state-specific quota of 2,807,200 pounds for the 2011/2012 fishing year, and the state set a maximum 3,000 pound per trip possession limit depending on fishing location.

Given the history of this fishery, continued increases in quotas and possession limits are anticipated. In October 2011, the Federal fishery management councils recommended to NMFS a 2012/2013 commercial quota of 35.7 million pounds and increased the per trip possession limit to 4,000 pounds. In November 2011, ASMFC set the 2012/2013 fishing year quota at 30 million pounds with a maximum daily possession limit of 3,000 pounds. North Carolina will receive a state-specific share of 4,210,800 pounds.

These recent increases in the quotas and possession limits resulted in increased effort in medium mesh gillnets targeting spiny dogfish, notably in North Carolina with its individual state quota. Despite increased effort and landings, medium mesh gillnet soak duration is unlikely to increase to pre-FMP durations because the possession limits are still relatively low (less than or equal to 3,000 pounds) and BDTRP nighttime medium mesh restrictions are in place. Federal fishery observer data for medium mesh gillnets targeting all species in North Carolina state waters during the winter show a marked decrease in soak durations since the spiny dogfish FMPs were implemented. Prior to implementation of the FMPs (1996–2000), soak durations ranged from less than one hour to 48 hours, averaging 9.6 hours. After the FMPs were implemented (2001–2010), soak durations ranged from less than one hour to 24 hours, averaging only 1.8 hours. Although the current average soak duration is still relatively low, Federal fishery observer data indicate some longer soak durations commensurate with increases in possession limits and quotas. Historically, bycatch of bottlenose dolphins was associated with long soak durations (average of 20 hours) of medium mesh gillnets targeting spiny dogfish in North Carolina. Thus, permanently extending the nighttime medium mesh gillnet restrictions will ensure soak durations do not increase back to historically high levels, increasing the risk of serious injury and mortality to bottlenose dolphins.

Bottlenose Dolphin Mortalities Associated With Medium Mesh Gillnets in North Carolina

The implementation of the spiny dogfish FMPs and subsequent effort reductions had the inadvertent but beneficial effect of reducing bottlenose dolphin serious injuries and mortalities in North Carolina; however, this trend may change as the fishery rebuilds and quotas continue to increase. From 1996 to 2000 in the North Carolina portion of the previously defined Winter-Mixed Management Unit (now corresponding to four different stocks; see the discussion in this rule under the heading, *Revisions to the Western North Atlantic Coastal Bottlenose Dolphin Stock*), medium mesh gillnets targeting spiny dogfish were the primary contributors to the total bottlenose dolphin mortality (Rossman and Palka 2004). The mean animal mortality for the entire Winter-Mixed Management Unit from 1996 to 2000 was 180, which exceeded the PBR of 68 (Waring *et al.* 2007; Rossman and Palka 2004). Sixty-three percent, or 146 of 180 bottlenose dolphin serious injuries and mortalities, were attributed to medium mesh gillnets primarily targeting spiny dogfish in the North Carolina portion of the Winter-Mixed Management Unit. Conversely, from 2001 to 2002 in the entire Winter-Mixed Management Unit, small (less than or equal to 5-inch (12.7 cm)) and large (greater than or equal to 7-inch (17.8 cm) stretched) mesh gillnets were the primary contributors to total bottlenose dolphin serious injury and mortality. During 2000 to 2001, estimated mean animal mortality decreased to 59 bottlenose dolphins, of which, only 19 (24%) were attributed to medium mesh gillnets in the North Carolina portion of the Winter-Mixed Management Unit. This reduction in estimated bottlenose dolphin mortality was a result of reduced landings and lower bycatch rates across all gillnet mesh size categories (small, medium, and large), which includes almost no effort in medium mesh gear targeting spiny dogfish following implementation of the FMPs (Rossman and Palka 2004).

The BDTRP winter nighttime prohibitions for medium mesh gillnets continue to be important for bottlenose dolphin conservation because they effectively limit soak times to approximately 12 hours, reducing risk of bycatch. Before implementation of the FMPs, long soak durations associated with medium mesh gillnets targeting spiny dogfish were a major contributing factor to high bottlenose dolphin bycatch rates in North Carolina. Federal observer data prior to FMP implementation document three bottlenose dolphin mortalities in medium mesh nets with soak times averaging 20 hours; only one mortality was in a net with a soak time of less than 12 hours. There have been no observed takes in medium mesh gillnets targeting spiny dogfish in North Carolina waters since 2000 when FMPs eliminated directed spiny dogfish fishing effort, and consequently, the need for long soak durations.

Stranding data also indicate the BDTRP winter nighttime medium mesh gillnet prohibitions are effective at reducing serious injury and mortality of bottlenose dolphins regardless of increases in the spiny dogfish quota. Byrd *et al.* (2008) compared the number of bottlenose dolphins that stranded in North Carolina coastal state waters with evidence of a fishery interaction during the winter from November 1997 through April 2005. They found stranding rates and bottlenose dolphin bycatch rates from Rossman and Palka (2004) were similar and corresponded to fluctuations in fishing effort for spiny dogfish in North Carolina. Specifically, for the time period examined, there was a significant positive relationship in the numbers of bottlenose dolphin strandings with signs of fishery interaction and bottlenose dolphin bycatch rate before and after the FMPs were implemented. Furthermore, the mean number of strandings with signs of a fishery interaction in North Carolina coastal state waters was greater before the FMPs were implemented (14.3 animals during November–April from 1997–2000) than after the FMPs (5.2 during November–April from 2001–2005) (Byrd *et al.* 2008). Therefore, in the absence of Federally observed takes since 2000, stranding data may be used as a proxy to detect increases in bottlenose dolphin bycatch mortality (Byrd *et al.* 2008). Updated stranding data from November 2005 through April 2010 show a continued trend in reduction of strandings with signs of a fishery interaction, with an average of 2.8 strandings in all North Carolina state waters (NOAA Southeast Stranding Data).

The nighttime medium mesh gillnet restrictions were initially included in the BDTRP to ensure long soak durations of medium mesh gillnets were modified to reduce serious injury and mortality rates. These restrictions were given expiration dates on two occasions to monitor the status of the spiny dogfish fishery and management. The BDTRP prohibitions ensure reduced soak durations in medium mesh gillnets despite a recent increase in spiny dogfish fishing effort in North Carolina as shown by: (1) Reduced soak durations in medium mesh gillnets in North Carolina state waters during the winter; and (2) a continued decreasing trend of bottlenose dolphin strandings with evidence of a fishery interaction in North Carolina state waters during the winter.

BDTRT Recommendations for Medium Mesh Gillnets in North Carolina

Following implementation of the BDTRP in May 2006, the BDTRT met on June 19–20, 2007, to monitor the effectiveness of the BDTRP. Among other things, the BDTRT was provided updates on spiny dogfish fishery management, landings, and gear practices since the team originally deliberated on the draft BDTRP. The BDTRT recommended by consensus that the nighttime medium mesh gillnet restrictions in North Carolina be extended for an additional three years and NMFS provide an update on the status of the spiny dogfish fishery at least biennially. Therefore, per the BDTRT's recommendation, NMFS amended the BDTRP in December 2008 with a new expiration date of May 26, 2012, for the nighttime medium mesh gillnet restrictions (73 FR 77531).

NMFS held another BDTRT meeting on September 9–11, 2009, to evaluate the BDTRP and review revisions to the bottlenose dolphin stock structure. The BDTRT was provided with updates on medium mesh gillnet fishing effort targeting spiny dogfish in North Carolina and FMP management addenda and quota changes. Because of recent changes to the FMPs, the recovering spiny dogfish population, and increased fishing effort in North Carolina, the BDTRT recommended by consensus that NMFS permanently include the nighttime medium mesh gillnet prohibitions in North Carolina. The BDTRT recognized the importance of these restrictions because of the historically high rates of bottlenose dolphin serious injury and mortality associated with medium mesh gillnets targeting spiny dogfish.

For several reasons, NMFS agrees the expiration date should be removed rather than continuing to extend the medium mesh restrictions for three-year durations. The spiny dogfish population was declared rebuilt in 2010, resulting in continued increased FMP quotas and possession limits, and landings of spiny dogfish in North Carolina. Federal fishery observer data indicate some longer soak durations commensurate with increases in quotas and possession limits. Historically, observed takes of bottlenose dolphins in North Carolina medium mesh gillnets targeting spiny dogfish were associated with longer soak durations, and 63 percent of bottlenose dolphin serious injuries and mortality were associated with medium mesh gillnets targeting spiny dogfish. Given these factors, permanently maintaining the BDTRP restrictions is necessary for meeting the goals of the plan, per the MMPA requirement to reduce serious injury and mortality of strategic bottlenose dolphin stocks in North Carolina.

Non-Regulatory Changes and Updates to the BDTRP

Non-Regulatory Management Measures and BDTRT Consensus Recommendations

This proposed rule also includes updates for non-regulatory components of the BDTRP. These updates are based on the BDTRT's consensus recommendations from their June 2007 and September 2009 meetings and do not represent a substantive change to the BDTRP requirements. The BDTRT recognized the effectiveness of the BDTRP requirements implementing non-regulatory actions, such as continued research, monitoring, enforcement of regulations, outreach, and other collaborative efforts. Non-regulatory measures are an important complement to the BDTRP's regulatory measures in achieving the plan's short-term goal and providing a framework for achieving the long-term goal.

Since the BDTRP's implementation in May 2006, NMFS convened two in-person meetings (June 2007 and September 2009) of the BDTRT to monitor and evaluate the BDTRP's effectiveness. At both meetings, the BDTRT provided NMFS with additional non-regulatory recommendations, which NMFS agrees are important to achieving the plan's goals. Some of these recommendations have already been accomplished because of the adaptive nature of the non-regulatory measures.

The following are summaries of proposed amendments to the BDTRP's non-regulatory management measures. Please see the **FOR FURTHER INFORMATION CONTACT** section for where to obtain the 2007 and 2009 BDTRT meeting summaries for details on these recommended measures.

Research

(1) Bottlenose Dolphin Research

Based on the spatial and temporal complexity of bottlenose dolphin stocks, the BDTRT advised NMFS in both 2007 and 2009 to support continued research to improve the understanding of bottlenose dolphin stock structure. The BDTRT specifically recommended using genetics, dorsal fin photo-identification, and telemetry data for continued refinement of bottlenose dolphin stock structure, abundance estimates, and PBR levels for all stocks and especially those occupying North Carolina waters. To identify fishery-related mortalities and serious injury to stock, the BDTRT further recommended using genetic samples or matching dorsal fin images to the Mid-Atlantic Bottlenose Dolphin Photo-Identification Catalog.

(2) Fishing Gear Research

Gear modification research, in cooperation with fishermen, is important to help reduce serious injury or mortality to bottlenose dolphins incidental to commercial fishing while maintaining those fisheries. Therefore, the BDTRP recommended the following: (1) Determine if pingers reduce depredation rates of bottlenose dolphins on gillnets and whether pingers affect bottlenose dolphins; (2) examine the ratio of net height versus water depth in gillnets targeting Spanish and king mackerel; and (3) continue exploring the effectiveness of modified leaders in the Virginia Pound Net fishery for maintaining catch efficiency, especially around Lynnhaven, Virginia.

Trap/Pot Fisheries

During the 2009 meeting, the BDTRT recognized trap/pot gear as the main commercial fishing gear interacting with some of the estuarine stocks of bottlenose dolphins. Stranding data indicate interactions with trap/pot gear are occurring with bottlenose dolphins, and only one or two takes may result in serious injury and mortality levels that exceed PBR for these small stocks. The BDTRT provided the following recommendations to better understand the nature of interactions with trap/pot gear, inform future discussions, and reduce potential serious injuries and mortalities of bottlenose dolphins: (1) Develop state programs to remove derelict trap/pot gear; (2) characterize trap/pot gear (e.g., amount of vertical line, gear markings, etc.) interacting with bottlenose dolphins, amount of fishing effort, spatial and temporal aspects of the fisheries, and types of gear modifications (e.g., inverted bait wells); and (3) host a technology transfer workshop for fishermen using blue crab trap/pot gear to explore gear modifications that may help reduce bottlenose dolphin interactions.

Monitoring and Evaluating Plan Effectiveness

(3) Outreach and Education

Continued education and outreach to affected Category I and II fishermen and stakeholders is necessary to enhance compliance with, and therefore the effectiveness of, the BDTRP. The BDTRT recommended outreach be maintained and conducted consistently. For example, NMFS fishery liaisons or mailings are effective approaches in consistently informing fishermen of any BDTRP updates. The BDTRT also recommended holding fishermen working groups to better understand the nature of bottlenose dolphin interactions with specific gear types, as fishermen can provide important knowledge in trends or patterns of interactions. The BDTRT further recognized the value of highlighting the success of the BDTRP if an affected stock reaches the MMPA long-term goal (i.e., serious injury and mortality is below 10 percent of a stock's PBR level). Using success stories as platforms for education and outreach is an important tool, especially when encouraging compliance with the plan regulations.

(4) Observer Program

The observer program is vital for measuring if take reduction plan regulations are effective in reducing serious injury and mortality of bottlenose dolphins and monitoring changes in interaction rates between bottlenose dolphins and affected fisheries. Previous BDTRT recommendations focused on enhancing and improving the overall precision and accuracy of observer data. Recent BDTRT meeting recommendations encouraged focusing observer coverage in specific geographic areas and fisheries, improving observer data collection and quality, and measures of fishing effort. Specifically, the BDTRT recommended enhancing and prioritizing observer coverage in: (1) The North Carolina beach seine fishery; (2) gillnets targeting Spanish mackerel in inshore waters of North Carolina; and

(3) gear operating in North Carolina state waters during the summer. Recommendations to improve documentation of observed takes were also provided. Specifically, the BDTRT recommended prioritizing documentation of dorsal fin images and collection of biopsy samples, or the entire carcass if possible, and detailed documentation of the entanglement event. Improved data collection will help in assigning mortality to a particular stock because of the spatial and temporal overlap of stocks, especially in North Carolina. Finally, the team recommended determining the accuracy of current fishing effort measures used for bottlenose dolphin mortality estimates by comparing alternate measures of fishing effort with current methods.

(5) Enforcement

Enforcement is important for compliance monitoring of take reduction plan regulations. If the plan is not reaching its goals, NMFS will determine if non-compliance is a factor. The BDTRT recommended coordination with state and other Federal agencies on enforcement activities.

(6) Adaptive Management

At the team's 2009 meeting, some abundance estimates and PBRs for stocks were unknown due to the recent revisions in bottlenose dolphin stock structure. However, the team noted at the meeting that the mortality estimate for the Northern North Carolina Estuarine System Stock may be approaching or exceeding PBR. The BDTRT recommended that after NMFS updates the abundance estimate and PBR for the stock, if PBR is determined to have been exceeded, the BDTRT be convened via conference call or in-person meeting to ensure more real-time communications and monitoring of the BDTRP's effectiveness. Having such discussions in real-time allows for an adaptive management approach to more quickly target potential reasons the BDTRP is not achieving its short-term goal and begin considering effective solutions.

Revisions to the Western North Atlantic Coastal Bottlenose Dolphin Stock

The Western North Atlantic coastal bottlenose dolphin morphotype is continuously distributed in estuarine and coastal waters along the United State's Atlantic coast. Based on spatial and temporal patterns in strandings during a die-off from 1987–1988, bottlenose dolphins in coastal waters along the Atlantic coast were designated as a single coastal stock (Western North Atlantic coastal bottlenose dolphin stock) that migrated seasonally between New Jersey and central Florida. This Western North Atlantic coastal bottlenose dolphin stock was considered strategic due to depletion during the 1987–1988 die-off and interactions with nine Category I and II commercial fisheries. The BDTRT was formed in 2001 and the BDTRP implemented in 2006 to reduce impacts from commercial fishing. The geographic scope and affected area of the BDTRP was based on the habitat and range of the Western North Atlantic coastal stock, including all tidal and marine waters within 6.5 nautical miles (12 km) of shore from the New York-New Jersey border southward to Cape Hatteras, North Carolina, and within 14.6 nautical miles (27 km) of shore from Cape Hatteras southward to, and including, the east coast of Florida.

During the BDTRT's initial deliberations in developing the draft BDTRP, research demonstrated the Western North Atlantic coastal bottlenose dolphin stock was not a single migratory stock, but rather a complex mosaic of stocks occupying estuarine and coastal waters. The stock was, therefore, separated into seven discrete management units with spatial and temporal components for purposes of developing the draft BDTRP. However, the entire range of the Western North Atlantic coastal stock was used for the geographic scope of the BDTRP. PBR, abundance estimates, and mortality estimates for the Western North Atlantic coastal stock were determined and assigned per management unit. These management units were used until additional data collection and analyses were completed to allow redefinition of discrete stocks (as opposed to seasonal management units) in 2009.

Genetic analyses, assessments of ranging patterns of bottlenose dolphins from long-term photographic identification studies, and satellite-telemetry tag studies were summarized to redefine stock structure. The stock structure now consists of nine estuarine system stocks and five coastal stocks. This description is not complete, however, because of insufficient information for some estuarine waters to evaluate stock structure, and limited information on the movement patterns of some of the coastal stocks. Targeted genetic studies showed genetic differentiation among coastal and estuarine stocks and separation between bottlenose dolphins occurring in estuarine versus coastal waters. Photo-identification studies described the seasonal ranging patterns of estuarine stocks and indicated some stocks (e.g., the Northern North Carolina Estuarine Stock) move offshore into nearshore coastal waters at particular times of year. Additionally, seasonal immigration/emigration and transient animals occur within estuaries, suggesting some degree of spatial overlap between estuarine and coastal animals (Waring *et al.* 2011). Although questions still remain about the degree of spatial overlap and mixing between the coastal and estuarine stocks, data indicates fourteen separate coastal and estuarine stocks are encompassed within the range of the Western North Atlantic morphotype of coastal bottlenose dolphins.

The Western North Atlantic coastal morphotype of bottlenose dolphins was, therefore, revised to include 14 stocks of coastal (five stocks) and estuarine (nine stocks) bottlenose dolphins instead of one previous migratory stock. All stocks within the coastal morphotype are still considered strategic, except the Florida Bay Stock. Therefore, thirteen of the 14 bottlenose dolphin stocks are affected under the BDTRP because they are strategic and interact with Category I and II commercial fisheries. The following is a list of the revised bottlenose dolphin stocks, along with a description of their spatial and/or temporal distributions as now included in the BDTRP (Waring *et al.* 2011):

1. Western North Atlantic Northern Migratory Coastal Stock, which occupies coastal waters from the shoreline to approximately the 25 meter isobath between the mouth of the Chesapeake Bay in Virginia and Long Island, New York during the summer months (July–September); and moves south occupying coastal waters from Cape Lookout, North Carolina to the Virginia/North Carolina border during the winter months (January–March).
2. Western North Atlantic Southern Migratory Coastal Stock, which occupies coastal waters north of Cape Lookout, North Carolina to the eastern shore of Virginia and potentially inside the Chesapeake Bay, Virginia during summer months (July–September); occupies waters south of Cape Lookout during the fall (October–December); moves as far south as northern Florida during the winter (January–March); and moves back north to occupy waters of North Carolina during the spring (April–June).
3. Western North Atlantic South Carolina/Georgia Coastal Stock, which occupies coastal waters year-round from the North Carolina/South Carolina border to the Georgia/Florida border.
4. Western North Atlantic Northern Florida Coastal Stock, which occupies

coastal waters year-round from the Georgia/Florida border to 29.4° N.

5. Western North Atlantic Central Florida Coastal Stock, which occupies coastal waters year-round from 29.4° N. to the western end of Vaca Key, Florida.

6. Northern North Carolina Estuarine System Stock, which occupies Pamlico Sound, North Carolina and nearshore coastal waters (less than 1 km from shore) of North Carolina to Virginia Beach during the summer and fall (July–October); moves out of the estuarine waters and occupies nearshore coastal waters (less than 1 km from shore) between Capes Lookout and Hatteras, North Carolina during the late fall and winter (November–March); and occupies nearshore coastal (less than 1 km from shore) and estuarine waters of southern North Carolina during the spring (April–June).

7. Southern North Carolina Estuarine System Stock, which occupies estuarine and nearshore coastal waters (less than 3 km from shore) between the North Carolina/South Carolina border and Core Sound, North Carolina during the summer and fall (July–October); and moves south to occupy coastal nearshore waters near Cape Fear, North Carolina during the late fall through spring (November–June).

8. Charleston Estuarine System Stock, which occupies the riverine and estuarine waters year-round from Prince Inlet, South Carolina to the north and the North Edisto River, South Carolina to the south.

9. Northern Georgia/Southern South Carolina Estuarine System Stock, which occupies all estuarine, riverine, and creek waters year-round from the southern extent of the North Edisto River, South Carolina to the northern extent of Ossabaw Sound, South Carolina.

10. Southern Georgia Estuarine System Stock, which occupies all estuarine, intracoastal waterways, sounds, rivers, and tributaries year-round from the Altamaha River, Georgia to the Cumberland River at the Georgia/Florida border.

11. Jacksonville Estuarine System Stock, which occupies all estuarine and riverine waters year-round from Cumberland Sound at the Florida/Georgia border to Jacksonville Beach, Florida.

12. Indian River Lagoon Estuarine System Stock, which occupies all estuarine, riverine and lagoon waters year-round from Ponce de Leon Inlet, Florida to Jupiter Inlet, Florida.

13. Biscayne Bay Stock, which occupies all estuarine waters year-round from Haulover Inlet, Florida to Card Sound Bridge.

To reflect updated knowledge and understanding of bottlenose dolphin stock structure, this proposed rule updates 50 CFR 229.35(a) by removing the reference to the ''Western North Atlantic bottlenose dolphin coastal stock'' and replacing it with ''stocks of bottlenose dolphins within the Western North Atlantic coastal morphotype''. Updating the bottlenose dolphin stocks included in the BDTRP will not modify management measures in the BDTRP. Although the management units were used to inform the development of the BDTRP, management measures in the BDTRP are still applicable based on the temporal and seasonal movements of each stock and Category I and II fisheries affected and regulated by the BDTRP. Each stock has its own abundance and mortality estimates, as well as associated PBRs. NMFS will continue monitoring serious injury and mortality for each stock through observer program and stranding data. NMFS will also continue evaluating the effectiveness of the BDTRP by monitoring serious injury and mortality estimates of bottlenose dolphins relative to the short- and long-term goals of the BDTRP.

Other Updates

Since finalizing and implementing the BDTRP in May 2006, two errors in the BDTRP implementing regulations were identified. This proposed rule corrects the two errors as follows: (1) The current boundary for Southern North Carolina State Waters and South Carolina in 50 CFR 229.35(b) uses North Carolina/South Carolina at the coast (33°52′ N.) for the southern part of the boundary. Similarly, the definition for South Carolina, Georgia, and Florida waters use the same latitude for the northern part of the boundary. The latitude 33°52′ N., however, does not accurately reflect the actual border. This proposed rule modifies the coordinate to accurately reflect the North Carolina/South Carolina border at the coast. The border for North Carolina/South Carolina would be defined as the latitude corresponding with 33°51′07.9″ N. at the coast as described by ''Off South Carolina'' in 50 CFR 622.2 of this title (Fisheries of the Caribbean, Gulf, and South Atlantic—Definitions and Acronyms); and (2) In the regulatory text implementing the BDTRP, both 50 CFR 229.35(d)(1)(i) and 229.35(d)(2)(i) describe regional management measures for New Jersey, Delaware, Maryland, and Virginia state waters specific to medium and large mesh gillnet gear. In specifying the regulated gear type, the word ''gillnet'' was not included in the titled description of the management measures, reading ''Medium and large mesh''. It is clear in the regulatory text these regulations are for both medium and large mesh gillnet gear. Therefore, this proposed rule corrects this omission in the two title descriptions by adding the word ''gillnet'', so the title would read ''Medium and large mesh gillnets'' for gear regulated under § 229.35(d)(1)(i) and 229.35(d)(2)(i).

Classification

This proposed rule has been determined to be not significant under Executive Order 12866.

NMFS determined this action is consistent to the maximum extent practicable with the enforceable policies of the approved coastal management program of North Carolina. This determination was submitted for review by the responsible state agencies under section 307 of the Coastal Zone Management Act on December 22, 2011. North Carolina concurred with the consistency determination in a letter dated January 23, 2012.

This action contains policies with federalism implications that were sufficient to warrant preparation of a federalism summary impact statement under Executive Order 13132 and a federalism consultation with officials in the state of North Carolina. Accordingly, the Assistant Secretary for Legislative and Intergovernmental Affairs provided notice of the proposed action to the appropriate officials in North Carolina.

NMFS determined this action is categorically excluded from the requirement to prepare an Environmental Assessment (EA) in accordance with sections 5.05b and 6.03c.3(i) of NOAA's Administrative Order (NAO) 216–6 for implementing the National Environmental Policy Act. Specifically, this proposed action, if implemented, permanently maintains, without modification, a current regulation that would not substantially change the regulation or have a significant impact on the environment. NMFS prepared an EA on the final rule (71 FR 24776, April 19, 2006) to implement the BDTRP, which included an analysis of the proposed action without time constraints. The EA analyzed all regulations in the final BDTRP of which the regulations addressed in this proposed rule were a component. The EA resulted in a finding of no significant impact. In accordance with section 5.05b of NAO 216–6, the proposed regulations were determined to not likely result in significant impacts as defined in 40 CFR 1508.27. This action does not trigger the exceptions to categorical exclusions listed in NAO 216–6, Section 5.05c. A categorical exclusion memorandum to the file has been prepared.

An Endangered Species Act section 7 consultation was conducted on this action and found that it may affect, but is not likely to adversely affect, threatened and endangered species. There is no designated critical habitat under NMFS' jurisdiction in the action area, so critical habitat was not affected. Furthermore, the only impacts from this action are expected to be beneficial to listed species because the proposed action will maintain reduced soak times in medium mesh gillnet fishing in North Carolina state waters.

This proposed rule does not contain collection-of-information requirements subject to the Paperwork Reduction Act.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows.

The purpose of this proposed rule is to continue reducing serious injuries and mortalities to bottlenose dolphins incidental to commercial fishing operations and ensure serious injuries and mortalities do not exceed PBR levels, as mandated by the MMPA. The MMPA provides the statutory basis for this proposed rule.

This proposed rule would not establish any new reporting, recordkeeping, or other compliance requirements. No duplicative, overlapping, or conflicting Federal rules have been identified.

Initial and final regulatory flexibility analyses, dated April 2006, were prepared for the BDTRP. These analyses determined all commercial fishing entities using medium mesh gillnets in the manner and location encompassed by the proposed action implementing the BDTRP would be affected. Because this rule, if implemented, would continue the existing restrictions on this gear sector, all entities using this gear would potentially be directly affected.

As detailed in the analyses for the 2006 BDTRP, a total of 1,321 unique participants were identified as having recorded landings using medium mesh gillnet gear during the 2001 fishing season (November 2000–October 2001) in North Carolina. Total harvests with this gear were valued at approximately $13.8 million (nominal ex-vessel value), or approximately 18% of total fishing revenues by these entities of approximately $77 million (nominal ex-vessel value). The average annual revenue from the harvest of all marine species by these vessels was approximately $58,000.

The Small Business Administration (SBA) has established size criteria for all major industry sectors in the U.S. including fish harvesters. A business involved in fish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $4.0 million (NAICS code 114111, finfish fishing) for all its affiliated operations worldwide. Based on the estimated average annual revenue of vessels using medium mesh gillnet gear in North Carolina from the 2001 fishing season, the analyses conducted for the BDTRP determined all entities expected to be affected by the proposed action were small business entities. Comparable average revenue estimates for current entities in North Carolina using medium mesh gillnet gear are not available. However, although time has elapsed since the initial BDTRP analyses, no information has been identified to suggest economic performance in this sector has substantially improved since 2001, and the disparity between the 2001 average ($58,000) and the SBA threshold ($4.0 million) is sufficiently large to conclude participants in this sector of the commercial fishery remain small business entities. As a result, all commercial entities expected to be directly affected by this proposed rule, if implemented, are determined for the purpose of this analysis to be small business entities.

Although this proposed rule, if implemented, would restrict the behavior of entities using medium mesh gillnets in North Carolina coastal state waters, it would not directly affect any current fishing revenues or fishing practices nor likely prevent fishermen from the harvesting the increasing spiny dogfish quotas as indicated below. The scope of this proposed rule is the same as analyzed in support of the 2006 BDTRP. As detailed in the analyses provided supporting the 2006 BDTRP, the initial implementation of the restriction was estimated to result in an estimated reduction in ex-vessel revenue of approximately $296,000, or less than 1% of total ex-vessel revenue for the affected entities. This low impact was likely affected by the decline in spiny dogfish harvests, which have historically been the primary target of this gear in North Carolina. Spiny dogfish harvests declined from approximately 3.5 million pounds in 2000 to less than 20,000 pounds per year in 2005 and 2006. As discussed in the preamble, landings of spiny dogfish in North Carolina began increasing in 2009. For the 2010–2011 fishing season, 181 vessels recorded spiny dogfish landings of approximately 1.71 million pounds valued at approximately $257,000. The recent increase in spiny dogfish harvests demonstrates fishermen have adapted their fishing practices and are successfully harvesting spiny dogfish despite the current BDTRP gear restrictions. Therefore, the proposed continuation of these restrictions would not cause fishermen to lose actual income, but would only preclude potential future income from fishing with medium mesh gillnets in the manner subject to this proposed regulation. Because this proposed rule, if implemented, would only continue the prohibition of a fishing practice that has not been used since 2006, current revenues or profits of any small entity would not be affected because this action is not expected to prohibit fishermen from harvesting spiny dogfish quotas. Further, current participants in the affected fishery have demonstrated the ability to successfully harvest the primary target species for the affected gear, and fishing revenues for the target species have been increasing despite the BDTRP restriction. Therefore, this proposed rule, if implemented, would not be expected to have a significant, direct adverse economic effect on the profits of a substantial number of small entities.

Because this proposed rule, if implemented, is not expected to have any direct adverse economic impact on a substantial number of small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

References Cited

ASMFC. 2002. Interstate Fishery Management Plan for Spiny Dogfish. Fishery Management Report No. 40 of the Atlantic States Marine Fisheries Commission. Prepared by the Spiny Dogfish Plan Development Team.

ASMFC. 2007. Review of the Atlantic States Marine Fisheries Commission's Interstate Fishery Management Plan for Spiny Dogfish (*Squalus acanthias*) May 2006–April 2007 fishing year. Prepared by the Spiny Dogfish Plan Review Team, ASMFC.

ASMFC. 2008. Addendum II to the Interstate Fishery Management Plan for Spiny Dogfish. Atlantic States Marine Fisheries Commission, approved October 2008.

ASMFC. 2011a. Addendum III to the Interstate Fishery Management Plan for Spiny Dogfish. Atlantic States Marine Fisheries Commission. April 2011.

ASMFC. 2011b. Review of the Atlantic States Marine Fisheries Commission's Interstate Fishery Management Plan for Spiny

Dogfish (*Squalus acanthias*) May 2009—April 2010 Fishing Year. Prepared by the Spiny Dogfish Plan Review Team, ASMFC.
Byrd, B.L, A.A. Hohn, F.H. Munden, G.N. Lovewell, and R.E. LoPiccolo. 2008. Effects of Commercial Fishing Regulations on Stranding Rates of Bottlenose Dolphins (*Tursiops truncatus*). Fish. Bull. 106:72–81.
NCDMF. 2008. Overview of North Carolina Spiny Dogfish Regulations and Commercial Landings. North Carolina Department of Natural Resources, March 2008.
NMFS. Personal Communication. National Marine Fisheries Service, Fisheries Statistic Division, Silver Spring, MD.
NMFS. 2006. 43rd SAW Assessment Summary Report (43rd SAW): 43rd SAW assessment report. US Dep Commer, Norteast Fish Sci Cent Ref Doc 06–25; 200. November 2006.
NOAA Southeast Stranding Data. 2010. NOAA National Marine Mammal Health and Stranding Response Database unpublished data, accessed March 1, 2011 date.
Rago, P.J. and K.A. Sosebee. 2010. Biological Reference Points for Spiny Dogfish. Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service. Northeast Fisheries Science Center Reference Document 10–06. May 2010.
Rossman, M. and D. Palka. 2004. A Review of Coastal Bottlenose Dolphin Bycatch Mortality Estimates in Relation to the Potential Effectiveness of the Proposed BDTRP. Prepared by NMFS–NEFSC for the BDTRT. BDTRT document number 1–13–05f.
Waring, G.T., E. Josephson, C.P. Fairfield-Walsh, and K. Maze-Foley, editors. 2007. U.S. Atlantic and Gulf of Mexico Marine Mammal Stock Assessments—2007. NOAA Tech Memo NMFS NE 205; 415 p.
Waring, G.T., E. Josephson, K. Maze-Foley, and P.E. Rosel, editors. 2011. U.S. Atlantic and Gulf of Mexico Marine Mammal Stock Assessments—2010. NOAA Tech Memo NMFS NE 219; 598 p.

List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: April 5, 2012.

Alan D. Risenhoover,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 229 is proposed to be amended as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

1. The authority citation for 50 CFR part 229 continues to read as follows:

Authority: 16. U.S.C. 1361 *et seq.;* 50 CFR 229.32(f) also issued under 16 U.S.C. 1531 *et seq.*

2. In § 229.35 paragraph (a), the definitions of *South Carolina, Georgia, and Florida waters* and *Southern North Carolina State waters* in paragraph (b), and paragraphs (d)(1)(i), (d)(2)(i), (d)(4)(ii), and (d)(5)(i) are revised to read as follows:

§ 229.35 Bottlenose Dolphin Take Reduction Plan.

(a) *Purpose and scope.* The purpose of this section is to implement the Bottlenose Dolphin Take Reduction Plan (BDTRP) to reduce incidental mortality and serious injury of stocks of bottlenose dolphins within the Western North Atlantic coastal morphotype in specific Category I and II commercial fisheries from New Jersey through Florida. Specific Category I and II commercial fisheries within the scope of the BDTRP are indentified and updated in the annual List of Fisheries. Gear restricted by this section includes small, medium, and large mesh gillnets. The geographic scope of the BDTRP is all tidal and marine waters within 6.5 nautical miles (12 km) of shore from the New York-New Jersey border southward to Cape Hatteras, North Carolina, and within 14.6 nautical miles (27 km) of shore from Cape Hatteras, southward to, and including the east coast of Florida down to the fishery management council demarcation line between the Atlantic Ocean and the Gulf of Mexico (as described in § 600.105 of this chapter).

(b) * * *

South Carolina, Georgia, and Florida waters means the area consisting of all marine and tidal waters, within 14.6 nautical miles (27 km) of shore, between 33°51′07.9″ N. (North Carolina/South Carolina border at the coast and as described by ''Off South Carolina'' in § 622.2 of this title) and the fishery management council demarcation line between the Atlantic Ocean and the Gulf of Mexico (as described in § 600.105 of this chapter).

* * * * *

Southern North Carolina State waters means the area consisting of all marine and tidal waters, within 3 nautical miles (5.56 km) of shore, bounded on the north by 34°35.4′ N. (Cape Lookout, North Carolina) and on the south by 33°51′07.9″ N. (North Carolina/South Carolina border at the coast and as described by ''Off South Carolina'' in § 622.2 of this title).

* * * * *

(d) * * *

(1) * * *

(i) *Medium and large mesh gillnets.* From June 1 through October 31, in New Jersey, Delaware, and Maryland State waters, no person may fish with any medium or large mesh anchored gillnet gear at night unless such person remains within 0.5 nautical mile (0.93 km) of the closest portion of each gillnet and removes all such gear from the water and stows it on board the vessel before the vessel returns to port.

* * * * *

(2) * * *

(i) *Medium and large mesh gillnets.* From June 1 through October 31, in Southern Virginia State waters and Northern Virginia State waters, no person may fish with any medium or large mesh anchored gillnet gear at night unless such person remains within 0.5 nautical mile (0.93 km) of the closest portion of each gillnet and removes all such gear from the water and stows it on board the vessel before the vessel returns to port.

* * * * *

(4) * * *

(ii) *Medium mesh gillnets.* From November 1 through April 30 of the following year, in Northern North Carolina State waters, no person may fish with any medium mesh gillnet at night.

* * * * *

(5) * * *

(i) *Medium mesh gillnets.* From November 1 through April 30 of the following year, in Southern North Carolina State waters, no person may fish with any medium mesh gillnet at night.

* * * * *

[FR Doc. 2012–8770 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 120213124–2225–01]

RIN 0648–BB91

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in a regulatory amendment to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) prepared by the Gulf of Mexico Fishery Management Council (Council). If implemented, this rule would increase the commercial and recreational quotas for red snapper in the Gulf of Mexico (Gulf) reef fish fishery for the 2012 fishing year, and for the 2013 fishing year if NMFS determines the acceptable biological catch (ABC) is not exceeded in the 2012 fishing year. This rule would also eliminate the October 1 closure date of the recreational fishing season. This proposed rule is intended to provide more flexibility in managing recreational red snapper and to help achieve optimum yield (OY) for the Gulf red snapper resource without increasing the risk of red snapper experiencing overfishing.

DATES: Written comments must be received on or before April 27, 2012.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2012–0024'' by any of the following methods:

- *Electronic submissions:* Submit electronic comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Cynthia Meyer, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter N/A in the required field if you wish to remain anonymous).

To submit comments through the Federal e-Rulemaking Portal: *http://www.regulations.gov,* enter ''NOAA–NMFS–2011–0024'' in the search field and click on ''search''. After you locate the proposed rule, click the ''Submit a Comment'' link in that row. This will display the comment web form. You can enter your submitter information (unless you prefer to remain anonymous), and type your comment on the web form. You can also attach additional files (up to 10MB) in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Comments received through means not specified in this rule will not be considered.

For further assistance with submitting a comment, see the ''Commenting'' section at *http://www.regulations.gov/#!faqs* or the Help section at *http://www.regulations.gov.*

Electronic copies of the regulatory amendment, which includes an environmental assessment and a regulatory impact review, may be obtained from the Southeast Regional Office Web Site at *http://sero.nmfs.noaa.gov/sf/GrouperSnapperandReefFish.htm.*

FOR FURTHER INFORMATION CONTACT: Cynthia Meyer, Southeast Regional Office, NMFS, telephone 727–824–5305; email: *Cynthia.Meyer@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Gulf reef fish fishery under the FMP. The Council prepared the FMP and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

The Southeast Data, Assessment, and Review (SEDAR) update assessment for Gulf red snapper, conducted in August 2009 (SEDAR 9), determined that overfishing had ended for the red snapper stock, and that the ABC may be increased. The stock, however, is still overfished and under a rebuilding plan through 2032. The next SEDAR benchmark stock assessment currently scheduled for Gulf red snapper is in 2012.

The Council's Scientific and Statistical Committee (SSC) met January 10–13, 2012, and recommended new ABCs for the 2012 and 2013 fishing years. For 2012, the SSC recommended an ABC of 8.080 million lb (3.665 million kg) and for 2013, the SSC recommended an ABC of 8.690 million lb (3.942 million kg). The Council met January 30–February 2, 2012, and voted to implement these new ABCs through the 2012 Gulf red snapper regulatory amendment.

Management Measures Contained in this Proposed Rule

This rule would set the 2012 and 2013 commercial and recreational quotas for red snapper based on the ABCs recommended by the SSC and on the current commercial and recreational allocations (51-percent commercial and 49-percent recreational). Therefore, the 2012 commercial quota would be set at 4.121 million lb (1.869 million kg), round weight, and the 2012 recreational quota would be set at 3.959 million lb (1.796 million kg), round weight. The 2013 quotas would be set at 4.432 million lb (2.010 million kg), round weight, for the commercial sector, and 4.258 million lb (1.931 million kg), round weight, for the recreational sector, if NMFS determines that the ABC is not exceeded in the 2012 fishing year. If NMFS determines the 2012 ABC is exceeded, NMFS will maintain the 2012 commercial and recreational quotas in the 2013 fishing year. If this is the case, the Assistant Administrator will file a notification with the Office of the Federal Register to announce that commercial and recreational quotas will remain at 2012 levels in the 2013 fishing year.

This rule would change the end of the recreational fishing season from October 1 to December 31. Under 50 CFR 622.34 (m), the red snapper recreational fishing season opens each year on June 1 and closes when the recreational quota is projected to be reached, but no later than October 1. Prior to June 1 each year, NOAA projects the closing date based on the previous year's data, and notifies the public of the closing date for the upcoming season. If subsequent data indicate the quota has not been reached by that closing date, NMFS may reopen the season, but only until the October 1 end date.

In 2010, following the closure of large areas of the Gulf in response to the Deepwater Horizon MC252 oil spill, NMFS determined the recreational quota was not caught during the open period. However, the October 1 end of the fishing season prevented NMFS from reopening the season to allow the remainder of the recreational quota to be caught. Instead, the Secretary had to take emergency action to reopen the season. Changing the end date of the fishing season to December 31 will allow NMFS to reopen the season through December 31, the end of the fishing year, thus maximizing this sector's opportunity to harvest its full quota and giving the Council and NMFS greater flexibility to manage the red snapper recreational fishing season.

In addition to proposing the change to the end of the fishing season, NMFS is currently reviewing preliminary landings information used in projecting recreational red snapper harvest for the 2012 fishing year. After finalized 2011 recreational landings data are available and before the season opens on June 1, 2012, NMFS will announce when the

2012 quota is projected to be harvested. NMFS may announce when the 2012 quota is projected to be harvested in the final rule associated with this action.

The red snapper management measures contained in this proposed rule would achieve the goal of National Standard 1 of the Magnuson-Stevens Act, which states that conservation and management measures shall prevent overfishing while achieving, on a continuing basis, the optimum yield for the fishery.

Other Changes to Codified Text

This rule also proposes to revise the definition for ''shrimp'' in the codified text, which was inadvertently not revised in a previous final rule. The final rule for Amendment 5 to the FMP for the Shrimp Fishery of the Gulf of Mexico (56 FR 22827, May 17, 1991) removed ''seabobs'' from the fishery management unit (FMU), however, the definition for ''shrimp'' in § 622.2 was not revised to remove ''seabobs'' at that time. Seabobs were never included in the FMU under the FMP for the Shrimp Fishery of the South Atlantic Region, and both FMP's management units are comprised of the same species. This rule would revise the definition of ''shrimp'' to correct NMFS' oversight.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

The purpose of this proposed rule is to eliminate the October 1 closure date of the recreational fishing season to provide more flexibility in managing recreational red snapper, set the 2012 commercial and recreational quotas for the red snapper component of the Gulf reef fish fishery, and set the 2013 commercial and recreational quotas for red snapper if NMFS determines the ABC is not exceeded in the 2012 fishing year. These proposed actions would be expected to increase the likelihood of achieving OY. The Magnuson-Stevens Act provides the statutory basis for this proposed rule.

This proposed rule, if implemented, would be expected to directly affect all commercial vessels and for-hire vessels that harvest red snapper. In order to harvest red snapper in excess of the bag limit and sell red snapper, a commercial reef fish permit and enough allocation in a fisherman's IFQ account is required. An estimated 920 vessels possess a commercial Gulf reef fish permit. However, over the period 2007–2010, only an average of 323 vessels per year recorded commercial red snapper harvests. As a result, for the purpose of this assessment, NMFs estimates that the number of potentially affected commercial vessels to range from 323–920. The average commercial vessel in the Gulf reef fish fishery is estimated to earn approximately $48,000 (all figures in 2010 dollars), while the average annual revenue for a vessel with red snapper landings was approximately $88,000 over the period 2007–2010.

A Federal Gulf reef fish for-hire vessel permit is required for for-hire vessels to harvest red snapper. On January 30, 2012, there were 1,377 valid (non-expired) or renewable reef fish for-hire vessel permits. An expired permit may not be actively fished, but is renewable for 1 year from the date of expiration. The for-hire fleet is comprised of charterboats, which charge a fee on a vessel basis, and headboats, which charge a fee on an individual angler (head) basis. Although the for-hire permit does not distinguish between headboats and charterboats, an estimated 69 headboats operate in the Gulf. The average charterboat is estimated to earn approximately $89,000 in annual revenue, while the average headboat is estimated to earn approximately $469,000.

No other small entities that would be expected to be directly affected by this proposed rule have been identified.

The Small Business Administration has established size criteria for all major industry sectors in the U.S., including fish harvesters and recreational services. A business involved in fish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $4.0 million (NAICS code 114111, finfish fishing) for all its affiliated operations worldwide. The revenue threshold for a business involved in the for-hire fishing industry is $7.0 million (NAICS code 713990, recreational industries). Based on the average revenue estimates provided above, NMFS determined that all commercial and for-hire vessels expected to be directly affected by this proposed rule are for the purpose of this analysis small business entities.

This proposed rule, if implemented, would not be expected to significantly reduce profits for a substantial number of small entities. This proposed rule would eliminate the October 1 closure date of the recreational fishing season, set the commercial and recreational quotas for 2012, and set the commercial and recreational quotas for 2013 if the ABC is not exceeded in the previous fishing year. At best, this action may result in increased operational efficiency and associated increased profits for for-hire entities associated with the recreational harvest of red snapper. The recreational red snapper season currently opens on June 1 and closes when the recreational sector quota is harvested, or is projected to be harvested, but no later than October 1. If the recreational quota is not harvested during this period, reopening the season would require additional regulatory action. Although the regulatory process required to reopen the season could, in theory, be completed in time to avoid a delay in reopening, i.e., the season could reopen on October 1, because of the administrative process, it is more likely that the season would end on October 1 and reopen later in the year. If this occurs, for-hire services associated with the recreational harvest of red snapper could not be continuously offered. Interruption of business could result in increased costs and operational inefficiencies, producing a net reduction in profits to for-hire entities despite a potentially unchanged number of total fishing trips and associated revenue. Eliminating the fixed October 1 closure date would be expected to increase the likelihood of an uninterrupted season, eliminating these operational inefficiencies, and potentially increasing profits. As a result, at best, this action may increase the likelihood of improved operational efficiency and increased profits to small entities.

NMFS notes, however, that this action, if implemented, would not likely have any direct economic effect on any small entities in the near-term or foreseeable future. Currently, the recreational red snapper season can remain open, if quota is available, through September 30 and this proposed rule would change this date to December 31. The recreational red snapper season in recent years, however, with the exception of 2010 when harvest was reduced as a result of the Deepwater Horizon MC252 oil spill, has not extended beyond July or August.

The 2011 season lasted 48 days, but the recreational quota was exceeded, and thus, the 2012 season is expected to be shorter. As a result, absent a reduction in the bag limit or other extreme circumstances that changes the effort, harvest rate, or availability of fish, the likelihood of the season extending to October 1 is not precisely known, but considered unlikely. Therefore, this action is not likely to have any direct economic effect on any small entities in the foreseeable future.

This proposed rule would also increase the combined commercial and recreational red snapper quotas in 2012 by 895,000 lb (405,965 kg) and by an additional 610,000 lb (276,691 kg) in 2013 (or a total increase of 1.505 million lb (0.683 million kg) over the 2011 combined commercial and recreational quotas), if the 2012 combined quota is not exceeded. These increases would be expected to result in an increase in revenue and profits to the affected commercial and for-hire fishing businesses.

In summary, this proposed rule, if implemented, would be expected to increase profits to all directly affected small entities.

Because this proposed rule, if implemented, would not be expected to have any direct adverse economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: April 6, 2012.

Alan D. Risenhoover,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 622.2, the definition for ''shrimp'' is revised to read as follows:

§ 622.2 Definitions and acronyms.

* * * * *

Shrimp means one or more of the following species, or a part thereof:

(1) Brown shrimp, *Farfantepenaeus aztecus.*

(2) White shrimp, *Litopenaeus setiferus.*

(3) Pink shrimp, *Farfantepenaeus duorarum.*

(4) Royal red shrimp, *Hymenopenaeus robustus.*

(5) Rock shrimp, *Sicyonia brevirostris.*

* * * * *

3. In § 622.34, paragraph (m) is revised to read as follows:

§ 622.34 Gulf EEZ seasonal and/or area closures.

* * * * *

(m) *Seasonal closure of the recreational sector for red snapper.* The recreational sector for red snapper in or from the Gulf EEZ is closed from January 1 through May 31, each year. During the closure, the bag and possession limit for red snapper in or from the Gulf EEZ is zero.

* * * * *

4. In § 622.42, paragraphs (a)(1)(i) and (a)(2)(i) are revised to read as follows:

§ 622.42 Quotas.

* * * * *

(a) * * *

(1) * * *

(i) *Red snapper.* (A) For fishing year 2012—4.121 million lb (1.869 million kg), round weight.

(B) For fishing year 2013—4.432 million lb (2.010 million kg), round weight.

* * * * *

(2) * * *

(i) *Recreational quota for red snapper.* (A) For fishing year 2012, the recreational quota for red snapper is 3.959 million lb (1.796 million kg), round weight.

(B) For fishing year 2013, the recreational quota for red snapper is 4.258 million lb (1.931 million kg), round weight.

* * * * *

[FR Doc. 2012–8756 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 120403254–2255–01]

RIN 0648–XB045

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Annual Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: NMFS proposes to implement the annual catch limit (ACL), harvest guideline (HG), annual catch target (ACT) and associated annual reference points for Pacific mackerel in the U.S. exclusive economic zone (EEZ) off the Pacific coast for the fishing season of July 1, 2011, through June 30, 2012. This rule is proposed according to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The proposed 2011/2012 ACL or maximum HG for Pacific mackerel is 40,514 metric tons (mt). The proposed ACT, which will be the directed fishing harvest target, is 30,386 mt. If the fishery attains the ACT, the directed fishery will close, reserving the difference between the ACL and ACT (10,128 mt) as a set aside for incidental landings in other CPS fisheries and other sources of mortality. This rule is intended to conserve and manage the Pacific mackerel stock off the U.S. West Coast.

DATES: Comments must be received by April 30, 2012.

ADDRESSES: You may submit comments on this document identified by NOAA–NMFS–2012–0072 by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov.* To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter NOAA–NMFS–2012–0072 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- *Mail:* Submit written comments to Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802.
- *Fax:* (562) 980–4047

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the report ''Pacific Mackerel (*Scomber japonicus*) Stock Assessment for USA Management in the 2011–12 Fishing Year'' and the Environmental Assessment/Regulatory Impact Review for this action may be obtained from the Southwest Regional Office (see **ADDRESSES**).

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, Southwest Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: During public meetings each year, the estimated biomass for Pacific mackerel is presented to the Pacific Fishery Management Council's (Council) Coastal Pelagic Species (CPS) Management Team (Team), the Council's CPS Advisory Subpanel (Subpanel) and the Council's Scientific and Statistical Committee (SSC), and the biomass and the status of the fisheries are reviewed and discussed. The biomass estimate is then presented to the Council along with the calculated overfishing limit (OFL) and available biological catch (ABC), annual catch limit (ACL) and harvest guideline (HG) and/or annual catch target (ACT) recommendations and comments from the Team, Subpanel and SSC. Following review by the Council and after hearing public comment, the Council adopts a biomass estimate and makes its catch level recommendations to NMFS.

This proposed rule would implement the 2011/2012 ACL, HG, ACT and other annual catch reference points, including OFL and an ABC that takes into consideration uncertainty surrounding the current estimate of biomass, for Pacific mackerel in the U.S. EEZ off the Pacific coast. (The EEZ off the Pacific Coast encompasses ocean waters seaward of the outer boundary of state waters, which is 3 nautical miles off the coast, out to a line 200 nautical miles from the coast.) The CPS FMP and its implementing regulations require NMFS to set these annual catch levels for the Pacific mackerel fishery based on the annual specification framework in the FMP. This framework includes a harvest control rule that determines the maximum HG, the primary management target for the fishery, for the current fishing season. The HG is based, in large part, on the current estimate of stock biomass. The harvest control rule in the CPS FMP is HG = [(Biomass-Cutoff) * Fraction * Distribution] with the parameters described as follows:

1. *Biomass.* The estimated stock biomass of Pacific mackerel age for the 2011/2012 management season is 211,126 mt.

2. *Cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 18,200 mt.

3. *Fraction.* The harvest fraction is the percentage of the biomass above 18,200 mt that may be harvested.

4. *Distribution.* The average portion (currently 70%) of the total Pacific mackerel biomass that is estimated to be in the U.S. EEZ off the Pacific coast, based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

At the June 2011 Council meeting, the Council adopted the 2011–12 Pacific mackerel assessment and a Pacific mackerel biomass estimate of 211,126 metric tons (mt). Based on recommendations from its SSC and other advisory bodies, the Council recommended and NOAA Fisheries (NMFS) is proposing, an OFL of 44,336 mt, an ABC of 42,375 mt, an ACL and maximum harvest guideline (HG) of 40,514 mt, and an ACT of 30,386 mt for the 2011/2012 Pacific mackerel fishing year. These catch specifications are based on the most recent stock assessment and the control rules established in the CPS FMP.

If the ACT is attained, the directed fishery will close, and the difference between the ACL and ACT (10,128 mt) will be reserved as a set aside for incidental landings in other CPS fisheries and other sources of mortality. In that event, for the remainder of the fishing year, incidental harvest measures will be in place, including a 45 percent incidental catch allowance when Pacific mackerel are landed with other CPS (in other words, no more than 45% by weight of the CPS landed per trip may be Pacific mackerel), except that up to 1 mt of Pacific mackerel could be landed without landing any other CPS. Upon the fishery attaining the ACL/HG (40,514 mt), no vessels in CPS fisheries may retain Pacific mackerel. The purpose of the incidental set-aside and allowance of an incidental fishery is to allow for the restricted incidental landings of Pacific mackerel in other fisheries, particularly other CPS fisheries, when the directed fishery is closed to reduce bycatch and allow for continued prosecution of other important CPS fisheries.

The NMFS Southwest Regional Administrator will publish a notice in the **Federal Register** announcing the date of any closure to either directed or incidental fishing.

Detailed information on the fishery and the stock assessment are found in the report ''Pacific Mackerel (*Scomber japonicus*) Stock Assessment for USA Management in the 2011–12 Fishing Year'' (see **ADDRESSES**).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law, subject to further consideration after public comment.

These proposed specifications are exempt from review under Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the reasons as follows:

The purpose of this proposed rule is to implement the 2011/2012 annual specifications for Pacific mackerel in the U.S. EEZ off the Pacific coast. The CPS FMP and its implementing regulations require NMFS to set an OFL, ABC, ACL and HG or ACT for the Pacific mackerel fishery based on the harvest control rules in the FMP. The specific harvest control rule is applied to the current stock biomass estimate to derive the annual HG, which is used to manage the commercial take of Pacific mackerel.

The U.S. Small Business Administration defines small businesses engaged in fishing as those vessels with annual revenues of or below $4 million. The small entities that would be affected by the proposed action are the vessels that compose the West Coast CPS finfish fleet. Pacific mackerel harvest is one component of CPS fisheries off the U.S. West Coast, which primarily includes the fisheries for Pacific sardine, northern anchovy and market squid. Pacific mackerel are principally caught off southern California within the limited entry portion (south of 39 degrees N. latitude; Point Arena, California) of the fishery. Sixty-four vessels are currently permitted in the Federal CPS limited entry fishery off California. The average annual per vessel revenue in 2010 for the West Coast CPS finfish fleet was well below $4 million; therefore, all of these vessels therefore are considered small businesses under the RFA. Because each affected vessel is a small business, this proposed rule has an equal effect on all of these small entities, and therefore will impact a substantial number of these small entities in the same manner. Accordingly, there would be no economic impacts resulting from disproportionally between small and large business entities under the proposed action.

The profitability of these vessels as a result of this proposed rule is based on the average Pacific mackerel ex-vessel price per mt. NMFS used average Pacific mackerel ex-vessel price per metric ton (mt) to conduct a profitability analysis because cost data for the harvesting operations of CPS finfish vessels was limited or unavailable.

For the 2010/2011 fishing year the HG was 11,000 metric tons (mt) and was divided into a directed fishery of 8,000 mt and an incidental fishery of 3,000 mt. Approximately 2,100 mt of this HG was harvested in 2010/2011 fishing season with an estimated ex-vessel value of $414,256 mt. Using these figures, the average 2010/2011 ex-vessel price per mt of Pacific mackerel was approximately $200.

The proposed ACL/HG for the 2011/2012 Pacific mackerel fishing season is 40,514 mt, with a directed fishing harvest target or ACT of 30,386 mt. This season's directed fishing target is more than 3 times higher than that of the previous year. If the fleet were to take the entire 2011/2012 ACT, and assuming a coastwide average ex-vessel price per mt of $206 (average of 2009 and 2010 ex-vessel), the potential revenue to the fleet would be approximately $6.3 million. However, this result will depend greatly on market forces within the fishery, and on the regional availability of the resource to the fleet and the fleets' ability to find schools of Pacific mackerel.

Over recent years, the profitability from fishing Pacific mackerel has depended less on the catch level, and more on market forces within the fishery as well as the other CPS fisheries, and on the regional availability of the species to the fleet and the fleets' ability to easily find schools relatively close to port. If there is no change in market conditions (i.e., an increase demand for Pacific mackerel product) or proximity of the fish to the fleet, it is not likely that the full ACT will be taken during the 2011–2012 fishing year, in which case profits will be lower than if the entire ACT were taken. The annual average U.S. Pacific mackerel harvest from 2001 to 2010 is approximately 4,500 mt, and over the last 10 years landings have averaged approximately 6,000 mt without exceeding 10,000 mt. As a result, it is unlikely that the ACT proposed in this rule will limit the potential profitability of the fleet from Pacific mackerel.

However, the revenue derived from harvesting Pacific mackerel is only one factor determining the overall revenue for a majority of the vessels in the CPS fleet, and, therefore, the economic impact to the fleet from the proposed action cannot be viewed in isolation. CPS vessels typically harvest a number of other species, including Pacific sardine, market squid, northern anchovy, and tuna, but focus on Pacific sardine, which had an estimated ex-vessel of $12.5 million in 2010, and market squid, which had an estimated ex-vessel of $71 million in 2010. Therefore, Pacific mackerel is only a small component of this multi-species CPS fishery and with the incidental catch provisions in this rule, the fleet will continue to be able to catch these other profitable species if the ACT is reached and directed mackerel fishing is closed.

Based on the disproportionality and profitability analysis above, this rule, if adopted, will not have a significant economic impact on a substantial number of these small entities. As a result, an Initial Regulatory Flexibility Analysis is not required, and none has been prepared.

There are no reporting, record-keeping, or other compliance requirements required by this proposed rule. Additionally, no other Federal rules duplicate, overlap or conflict with this proposed rule.

This action does not contain a collection-of-information requirement for purposes of the Paper Reduction Act.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 6, 2012.

Alan D. Risenhoover,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2012–8857 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 77, No. 71

Thursday, April 12, 2012

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

April 9, 2012.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC, *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Forest Service

Title: Understanding Value Trade-Offs Regarding Fire Hazard Reduction Programs in the Wildland-Urban Interface.

OMB Control Number: 0596–0189.

Summary of Collection: The Healthy Forests Restoration Act (Pub. L. 108–148), improves the ability of the Secretary of Agriculture and the Secretary of the Interior to plan and conduct hazardous fuels reduction projects on National Forest System and Bureau of Land Management Lands. The Forest Service, Bureau of Land Management, Bureau of Indian Affairs, National Park Service, Fish and Wildlife Service, and many State agencies with fire protection responsibilities have undertaken a very ambitious and expensive forest fuels reduction program. The Forest Service (FS) and university researchers will contact recipients of a phone/mail questionnaire to help forest and fire managers understand value trade-offs regarding fire hazard reduction programs in the wildland-urban interface.

Need and Use of the Information: Through the questionnaire, researchers will evaluate the responses of California and Colorado residents to different scenarios related to fire hazard reduction programs, how residents think the programs presented to them are effective, and calculate how much residents would be willing to pay to implement the alternatives. The collected information will help researchers provide better information to natural resources, forest, and fire managers when they are contemplating the kind and type of fire hazard reduction programs to implement to achieve forest land management planning objectives. Without the information the agencies with fire protection responsibilities will lack the capability to evaluate the general public's understanding of proposed fuels reduction projects and programs or their willingness to pay for implementing such programs.

Description of Respondents: Individuals or households.

Number of Respondents: 1,000.

Frequency of Responses: Reporting: Other (One time only).

Total Burden Hours: 584.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2012–8814 Filed 4–11–12; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–928]

Uncovered Innerspring Units From the People's Republic of China: Final Results and Final Rescission, in Part, of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 6, 2011, the Department of Commerce (''Department'') published in the **Federal Register** the *Preliminary Results* of the second administrative review of the antidumping duty order on uncovered innersprings units (''innersprings'') from the People's Republic of China (''PRC'').[1] We gave interested parties an opportunity to comment on the *Preliminary Results.* None were received. As such, these final results do not differ from the *Preliminary Results.* We find that Reztec Industries Sdn Bhd (''Reztec'') did not sell subject merchandise during the period of review (''POR''), February 1, 2010, through January 31, 2011 and, thus we are rescinding the administrative review, in part, with respect to Reztec. We additionally find that Goodnite Sdn Bhd (''Goodnite'') failed to cooperate to the best of its ability when it did not respond to the Department's original questionnaire and, therefore, we have assigned Goodnite's a rate based on total adverse facts available (''AFA''). The final dumping margin for this administrative review is listed in the ''Final Results of Review'' section below.

DATES: Effective April 12, 2012.

FOR FURTHER INFORMATION CONTACT: Susan Pulongbarit, AD/CVD Operations,

[1] *See Uncovered Innerspring Units from the People's Republic of China: Preliminary Results and Preliminary Rescission, in Part, of the Antidumping Duty Administrative Review,* 76 FR 76126 (December 6, 2011) (''*Preliminary Results''*).

Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4031.

SUPPLEMENTARY INFORMATION:

Background

As noted above, on December 6, 2011, the Department published in the **Federal Register** the *Preliminary Results* of the administrative review of innersprings from the PRC. The Department did not receive comments from interested parties on the *Preliminary Results.*

Changes Since the Preliminary Results

We have not made any changes to the *Preliminary Results.*

Scope of the Order

The merchandise subject to the order is uncovered innerspring units composed of a series of individual metal springs joined together in sizes corresponding to the sizes of adult mattresses (*e.g.,* twin, twin long, full, full long, queen, California king and king) and units used in smaller constructions, such as crib and youth mattresses. All uncovered innerspring units are included in the scope regardless of width and length. Included within this definition are innersprings typically ranging from 30.5 inches to 76 inches in width and 68 inches to 84 inches in length. Innersprings for crib mattresses typically range from 25 inches to 27 inches in width and 50 inches to 52 inches in length.

Uncovered innerspring units are suitable for use as the innerspring component in the manufacture of innerspring mattresses, including mattresses that incorporate a foam encasement around the innerspring.

Pocketed and non-pocketed innerspring units are included in this definition. Non-pocketed innersprings are typically joined together with helical wire and border rods. Non-pocketed innersprings are included in this definition regardless of whether they have border rods attached to the perimeter of the innerspring. Pocketed innersprings are individual coils covered by a ''pocket'' or ''sock'' of a nonwoven synthetic material or woven material and then glued together in a linear fashion.

Uncovered innersprings are classified under subheading 9404.29.9010 and have also been classified under subheadings 9404.10.0000, 7326.20.0070, 7320.20.5010, or 7320.90.5010 of the Harmonized Tariff Schedule of the United States (''HTSUS''). The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the order is dispositive.

Final Partial Rescission

In the *Preliminary Results,* the Department preliminarily rescinded the review with respect to Reztec.[2] In this administrative review, Reztec reported that it had no shipments of subject merchandise to the United States during the POR. As a result, the Department issued a no-shipment inquiry to U.S. Customs Border and Protection (''CBP''), asking that CBP provide any information contrary to our preliminary findings of no entries of subject merchandise for merchandise manufactured and shipped by Reztec.[3] We did not receive any response from CBP, thus indicating that there were no entries of subject merchandise into the United States exported by Reztec. After issuing the *Preliminary Results,* the Department did not receive any comments from interested parties regarding the rescission of this company. Therefore, the Department is rescinding the administrative review with respect to Reztec.

Final Results of Review

The dumping margin for the POR is as follows:

INNERSPRINGS FROM THE PRC

Manufacturer/Exporter	Margin (percent)
Goodnite[4]	234.51

Assessment

Upon issuance of the final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. Pursuant to 19 CFR 351.212(b)(1), we will calculate importer-specific (or customer) *ad valorem* duty assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales. In accordance with 19 CFR 351.106(c)(2), we will instruct CBP to liquidate, without regard to antidumping duties, all entries of subject merchandise during the POR for which the importer-specific assessment rate is zero or *de minimis.*

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 234.51 percent; (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter; and (4) for Goodnite the cash deposit rate will be 234.51 percent. These deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

In accordance with 19 CFR 351.305(a)(3), this notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under the APO, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested.

[2] *See id.,* at 76127.

[3] *See* Memoranda to Michael Walsh, Director, AD/CVD/Revenue Policy & Programs, from Jim Doyle, Office Director, dated between October 28, 2010, to December 17, 2010, Request for U.S. Entry Documents: Certain Steel Nails from the People's Republic of China.

[4] The Department notes that this antidumping duty margin applies only to Goodnite's subject merchandise, which is limited to PRC-origin merchandise. *See Preliminary Results* at 76127.

Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: April 3, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2012–8863 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–808]

Stainless Steel Plate in Coils From Belgium: Notice of Final Results of Antidumping Duty Changed Circumstances Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the ''Department'') has determined that Aperam Stainless Belgium N.V. (''Aperam'') is the successor-in-interest to ArcelorMittal Stainless Belgium N.V. (''AMSB''). As a result, Aperam will be accorded the same treatment previously accorded AMSB with regard to the antidumping duty order on stainless steel plate in coils from Belgium (''SSPC from Belgium''), effective as of the date of publication of this notice in the **Federal Register**.

DATES: Effective April 12, 2012.

FOR FURTHER INFORMATION CONTACT: George McMahon or Stephanie Moore, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1167 and (202) 482–3692, respectively.

Background

On May 21, 1999, the Department published in the **Federal Register** an antidumping duty order on stainless steel plate in coils from Belgium.[1] On June 14, 2011, Aperam filed a request for a changed circumstances review of the antidumping duty order on SSPC from Belgium. Aperam claimed that it is the successor-in-interest to AMSB and should be treated as such for purposes of the antidumping duty order.

On July 29, 2011, the Department published its initiation of the instant changed circumstances review of the antidumping duty order on SSPC from Belgium.[2]

On October 26, 2011, the Department published its preliminary results of changed circumstances review of the *AD Order* on SSPC from Belgium.[3] The Department preliminarily determined that Aperam is the successor-in-interest to AMSB and should be treated as such for purposes of the antidumping duty order. In the *Preliminary Results,* we stated that interested parties could submit case briefs to the Department no later than 30 days after the publication of the *Preliminary Results* in the **Federal Register**, and submit rebuttal briefs seven days subsequent to the due date of the case briefs. Aperam submitted a case brief on November 23, 2011, and no interested parties submitted a rebuttal brief.

Analysis of Comments Received

The issue raised in Aperam's case brief is addressed in the ''Issues and Decision Memorandum for the Final Results of the Changed Circumstances Review of the Antidumping Duty Order on Stainless Steel Plate in Coils from Belgium,'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, (''Issues and Decision Memorandum''),[4] dated concurrently with this notice and which is hereby adopted by this notice. A list of the issues which parties have raised, and to which we have responded in the Issues and Decision Memorandum, is attached to this notice as an Appendix.

Scope of the Antidumping Duty Order

The product covered by this order is certain stainless steel plate in coils. Stainless steel is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject plate products are flat-rolled products, 254 mm or over in width and 4.75 mm or more in thickness, in coils, and annealed or otherwise heat treated and pickled or otherwise descaled. The subject plate may also be further processed (*e.g.,* cold-rolled, polished, *etc.*) provided that it maintains the specified dimensions of plate following such processing. Excluded from the scope of this order are the following: (1) Plate not in coils; (2) Plate that is not annealed or otherwise heat treated and pickled or otherwise descaled; (3) Sheet and strip; and (4) Flat bars.

The merchandise subject to this order is currently classifiable in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheadings: 7219.11.00.30, 7219.11.00.60, 7219.12.00.06, 7219.12.00.21, 7219.12.00.26, 7219.12.00.51, 7219.12.00.56, 7219.12.00.66, 7219.12.00.71, 7219.12.00.81, 7219.31.00.10, 7219.90.00.10, 7219.90.00.20, 7219.90.00.25, 7219.90.00.60, 7219.90.00.80, 7220.11.00.00, 7220.20.10.10, 7220.20.10.15, 7220.20.10.60, 7220.20.10.80, 7220.20.60.05, 7220.20.60.10, 7220.20.60.15, 7220.20.60.60, 7220.20.60.80, 7220.90.00.10, 7220.90.00.15, 7220.90.00.60, and 7220.90.00.80. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to these orders is dispositive.

Final Results of Changed Circumstances Review

Based on the information provided by Aperam, the Department's analysis in the *Preliminary Results* (which we incorporate herein by reference), and in light of the fact that no interested parties submitted any comments on the Department's preliminary finding with respect to Aperam, the Department hereby determines that Aperam is the successor-in-interest to AMSB and is entitled to AMSB's treatment under the order. The Department will rely on the date of the publication of these final results of the instant changed circumstances review in the **Federal**

---

[1] *See Antidumping Duty Orders; Certain Stainless Steel Plate in Coils From Belgium, Canada, Italy, the Republic of Korea, South Africa, and Taiwan,* 64 FR 27756 (May 21, 1999), amended by *Notice of Amended Antidumping Duty Orders; Certain Stainless Steel Plate in Coils From Belgium, Canada, Italy, the Republic of Korea, South Africa, and Taiwan,* 68 FR 11520 (March 11, 2003); *Notice of Amended Antidumping Duty Orders; Certain Stainless Steel Plate in Coils From Belgium, Canada, Italy, the Republic of Korea, South Africa, and Taiwan,* 68 FR 16117 (April 2, 2003); and *Notice of Correction to the Amended Antidumping Duty Orders; Certain Stainless Steel Plate in Coils From Belgium, Canada, Italy, the Republic of Korea, South Africa, and Taiwan,* 68 FR 20114 (April 24, 2003).

[2] *See Stainless Steel Plate in Coils From Belgium: Notice of Initiation of Antidumping Duty Changed Circumstances Review,* 76 FR 45511 (July 29, 2011).

[3] *See Stainless Steel Plate in Coils from Belgium: Notice of Preliminary Results of Antidumping Duty Changed Circumstances Review* 76 FR 66271 (October 26, 2011) (''*Preliminary Results''*).

[4] The Issues and Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available in the Central Records Unit, main Commerce Building, Room 7046. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn/.* The signed Issues and Decision Memorandum and electronic version of the Issues and Decision Memorandum are identical in content.

Register as the effective date of this determination.

Instructions to U.S. Customs and Border Protection

We will instruct U.S. Customs and Border Protection to apply the cash-deposit rate in effect for AMSB to all entries of the subject merchandise from Aperam that were entered, or withdrawn from warehouse, for consumption on or after the date of publication of these final results of the changed circumstances review.

Notifications

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Tariff Act of 1930, as amended, and 19 CFR 351.216(e).

Dated: April 4, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I

List of Comments in the Issues and Decision Memorandum

Comment 1: Retroactive Application of the Final Results

[FR Doc. 2012–8864 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–898]

Chlorinated Isocyanurates From the People's Republic of China: Final Results of Antidumping Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On November 15, 2011, the Department of Commerce (the Department) published in the **Federal Register** the preliminary rescission of the antidumping duty new shipper review (NSR) of chlorinated isocyanurates from the People's Republic of China (PRC) for Heze Huayi Chemical Co. Ltd. (Heze Huayi).[1] We gave interested parties an opportunity to comment on the preliminary rescission. Based on our analysis of the comments received, we now are assigning Heze Huayi its own rate for these final results. *See* ''Final Results of Review'' section below.

DATES: Effective April 12, 2012.

FOR FURTHER INFORMATION CONTACT: Jun Jack Zhao, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1396.

SUPPLEMENTARY INFORMATION: We preliminarily rescinded the NSR for Heze Huayi on November 15, 2011. *See Preliminary Results.* In the preliminary rescission notice, the Department stated that interested parties were to submit case briefs within 30 days of publication of the *Preliminary Results* and rebuttal briefs within five days after the due date for filing case briefs. We received a case brief from Heze Huayi on December 16, 2011; we received a rebuttal brief from the Clearon Corp. and Occidental Chemical Corporation (collectively, Petitioners) on December 22, 2011.[2] On December 15, 2011, we received a hearing request from Heze Huayi, pursuant to 19 CFR 351.310(c). Also on December 15, 2011, Petitioners filed a request to participate in a hearing should one be requested by another party. On January 18, 2012, we conducted a closed session hearing concerning Heze Huayi's unreported sales that led to the Department's preliminary rescission of the NSR. On February 1, 2012, the Department extended the time limit for the final results of the NSR.[3] On February 22, 2012, Heze Huayi submitted a ''Notice of New Authority'' following the U.S. Court of International Trade (CIT) opinion[4] concerning the final results of the third NSR of the antidumping duty order of certain frozen fish fillets from the Socialist Republic of Vietnam,[5] Petitioners filed a rebuttal response to the ''Notice of New Authority'' submission on February 29, 2012.

Period of Review

Pursuant to 19 CFR 351.214(g), the period of review (POR) for this NSR is June 1, 2010, through December 31, 2010.

Scope of the Order

The products covered by the order are chlorinated isocyanurates, which are derivatives of cyanuric acid, described as chlorinated *s*-triazine triones. There are three primary chemical compositions of chlorinated isocyanurates: (1) Trichloroisocyanuric acid ($Cl_3(NCO)_3$), (2) sodium dichloroisocyanurate (dihydrate) ($NaCl_2(NCO)_3(2H_2O)$), and (3) sodium dichloroisocyanurate (anhydrous) ($NaCl_2(NCO)_3$). Chlorinated isocyanurates are available in powder, granular, and tableted forms. The order covers all chlorinated isocyanurates.

Chlorinated isocyanurates are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.40.50, 3808.50.40 and 3808.94.5000 of the Harmonized Tariff Schedule of the United States (HTSUS). The tariff classification 2933.69.6015 covers sodium dichloroisocyanurates (anhydrous and dihydrate forms) and trichloroisocyanuric acid. The tariff classifications 2933.69.6021 and 2933.69.6050 represent basket categories that include chlorinated isocyanurates and other compounds including an unfused triazine ring. Although the HTSUS subheadings are provided for convenience and customs purposes, the

[1] *See Chlorinated Isocyanurates from the People's Republic of China: Preliminary Rescission of Antidumping Duty New Shipper Review,* 76 FR 70705 (November 15, 2011) (*Preliminary Results*).

[2] Petitioners filed an extension request for filing their rebuttal brief until December 22, 2011, and the Department granted the extension request.

[3] *See Chlorinated Isocyanurates From the People's Republic of China: Extension of Time Limit for Final Results of Antidumping Duty New Shipper Review,* 77 FR 4990 (February 1, 2012).

[4] *See Hiep Thanh Seafood Joint Stock Co.* v. *United States,* Consol. Court No. 09–00270, Slip Op. 12–19 (February 15, 2012).

[5] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of the Third New Shipper Reviews,* 74 FR 29473 (June 22, 2009), and *Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Amended Final Results of New Shipper Review* 74 FR 37188 (July 28, 2009).

written description of the scope of the order is dispositive.

Use of Facts Otherwise Available

Section 776(a) of Tariff Act of 1930, as amended (the Act) provides that the Department shall apply ''facts otherwise available'' (FA) if, *inter alia,* necessary information is not on the record. Because we do not have complete sales and factors of production information for certain U.S. sales, the Department has based the antidumping duty margin for Heze Huayi on FA. While section 776(b) of the Act provides for the use of an adverse inference in applying FA in certain circumstances, the Department has determined that no such circumstances are at issue here that would warrant the use of an adverse inference. Therefore, as FA, we are applying the rate of 2.66 percent, which is the rate applied to Hebei Jiheng Chemical Company, Ltd. in the most recently completed administrative review.[6] For a complete discussion, *see* Memorandum to Paul Piquado, Assistant Secretary for Import Administration, ''Issues and Decision Memorandum for the Final Results of the New Shipper Review of Chlorinated Isocyanurates from the People's Republic of China: Heze Huayi Chemical Co., Ltd.,'' (Decision Memorandum), dated concurrently with, and hereby adopted by, this notice. A list of the issues addressed in the Decision Memorandum is appended to this notice. The Decision Memorandum is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Services System (IA ACCESS). IA ACCESS is available in the Central Records Unit, room 7046 of the main Commerce building. In addition, a complete version of the Decision Memorandum is accessible on the Web at *http://ia.ita.doc.gov/frn.* The signed Decision Memorandum and the electronic versions of the Decision Memorandum are identical in content.

When the Department relies on secondary information rather than on information obtained in the course of an investigation or review, section 776(c) of the Act provides that, to the extent practicable, the Department shall corroborate that information from independent sources that are reasonably at its disposal. Secondary information is defined as information derived from the petition, the final determination concerning the subject merchandise, or any previous review under section 751 of the Act concerning the subject merchandise. To corroborate means that the Department will satisfy itself that the secondary information to be used has probative value.[7] To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used.[8]

The FA rate of 2.66 percent selected for Heze Huayi is based on information submitted in a previous segment of this proceeding, the 2008–2009 administrative review. It is a calculated rate based solely on the questionnaire responses of the mandatory respondent in that review from the immediately preceding review period. Given that this rate is based on recent information submitted by a cooperative respondent producer of the subject merchandise under this same order, we find that the rate is reliable and relevant for use in this administrative review. Therefore, it has probative value for use as FA. As such, the Department finds this rate to be corroborated to the extent practicable, consistent with section 776(c) of the Act.

Changes Since the Preliminary Results

Based on our analysis of all of the comments and information on the record, the Department has decided not to maintain its preliminary rescission results for these final results. In the *Preliminary Results,* the Department found that Heze Huayi failed to report its first sale to the United States which it was required to report pursuant to 19 CFR 351.214(b)(2). For these final results, the Department determines that Heze Huayi could have reasonably concluded that it was not required to report this sale. Accordingly, the Department is not rescinding this review but, instead, assigning Heze Huayi a dumping margin. Because the Department does not have the necessary factors of production data for all sales, we are instead assigning Heze Huayi, based on FA pursuant to section 776 of the Act, the most recently calculated weighted-average margin for a review under this order, 2.66 percent. A full discussion of this decision is set forth in the Decision Memorandum, referred to above.

Final Results of Review

As a result of our review, we determine the following antidumping margin exists for the period June 1, 2010, through December 31, 2010.

Manufacturer/Exporter	Weighted-average margin (percent)
Heze Huayi Chemical Co. Ltd. ...	2.66

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this NSR. The Department will direct CBP to assess importer-specific assessment rates based on the *ad valorem* rate on each entry of the subject merchandise during the POR. The Department intends to issue assessment instructions directly to CBP 15 days after the publication of this notice.

Cash Deposit Requirements

Effective upon publication of the final results of the NSR, we will instruct CBP to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of subject merchandise exported by Heze Huayi. The following cash deposit requirements will be effective for all shipments of subject merchandise by Heze Huayi, entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of Act: (1) For subject merchandise produced and exported by Heze Huayi, the cash deposit rate will be the percent listed above, or the equivalent per-unit rate; (2) for subject merchandise exported by Heze Huayi, but not manufactured by Heze Huayi, the cash deposit rate will continue to be the PRC-wide rate of 285.63 percent; and (3) for subject merchandise manufactured by Heze Huayi, but exported by any party other than Heze Huayi, the cash deposit rate will be the rate applicable to the exporter. These cash deposit requirements will remain in effect until further notice.

---

[6] *See Chlorinated Isocyanurates from the People's Republic of China: Final Results of 2008–2009 Antidumping Duty Administrative Review,* 75 FR 70212 (November 17, 2010).

[7] *See id.*

[8] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan: Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews,* 61 FR 57391, 57392 (November 6, 1996), unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan: Final Results of Antidumping Duty Administrative Reviews and Termination in Part,* 62 FR 11825 (March 13, 1997).

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These final results and this notice are issued and published in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act.

Dated: April 5, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

Issues in the Decision Memorandum

Comment 1: Whether the Department's Preliminary Determination to Rescind the New Shipper Review Was Correct

Comment 2: Whether the Department Properly Analyzed Heze Huayi's Unreported Sales

Comment 3: Whether Heze Huayi's Final Antidumping Duty Rate Should Be the PRC-entity Rate

[FR Doc. 2012–8865 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–878]

Saccharin From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Intent To Rescind in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: April 12, 2012.

SUMMARY: The U.S. Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on saccharin from the People's Republic of China (''PRC'') for the period of review (''POR'') July 1, 2010, through June 30, 2011, covering 12 manufacturers/exporters of subject merchandise from the PRC.[1] The Department intends to rescind the review with respect to Kingchem LLC (''Kingchem''), for which the request for review was timely withdrawn. The Department preliminarily finds that, because none of the companies located in the PRC established eligibility for a separate rate, they will be treated as part of the PRC-wide entity. The Department also finds that the third-country exporters, because they do not have individual exporter rates, will continue to be subject to the cash deposit and assessment rates applicable to their PRC suppliers, in accordance with the Department's longstanding practice.[2]

We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act'').

FOR FURTHER INFORMATION CONTACT: Paul Stolz, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4474.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2011, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on saccharin from the PRC for the period July 1, 2010 through June 30, 2011.[3] On July 28, 2011, the Department received a timely request from Kinetic Industries (''Kinetic''), in accordance with 19 CFR 351.213(b), for an administrative review of this order. Kinetic submitted a second timely request on July 29, 2011, naming a twelfth respondent. On August 26, 2011, in accordance with section 751(a) of the Tariff Act of 1930, as amended (''the Act''), the Department published in the **Federal Register** the initiation notice of this antidumping duty administrative review with respect to the 12 companies covered by Kinetic's requests for review.[4] On October 25, 2011, the Department placed on the record U.S. Customs and Border Protection (''CBP'') import data which indicates that none of the companies named in the *Initiation* had suspended entries of subject merchandise into the United States during the POR.[5]

The Department invited comments regarding the CBP data and respondent selection but received none. In addition, the Department issued a no-shipment inquiry to CBP on December 21, 2011, covering the companies located in the PRC and the third-country exporters (except Kingchem).[6] The inquiry requested CBP to report any evidence of shipments during the POR by these companies but did not request a response if no such evidence exists. The Department did not receive a response from CBP.

Scope of the Order

The product covered by this antidumping duty order is saccharin. Saccharin is defined as a non-nutritive sweetener used in beverages and foods, personal care products such as toothpaste, table top sweeteners, and animal feeds. It is also used in metalworking fluids. There are four primary chemical compositions of saccharin: (1) Sodium saccharin (American Chemical Society Chemical

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Revocation in Part,* 76 FR 53404 (August 26, 2011) (''*Initiation*'').

[2] *See e.g., Chrome-Plated Lug Nuts From the People's Republic of China; Final Results of Antidumping Administrative Review,* 60 FR 48687 (September 20, 1995) and *Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results and Partial Rescission of the Seventh Antidumping Duty Administrative Review,* 77 FR 15039 (March 14, 2012).

[3] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 76 FR 38609 (July 1, 2011).

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 76 FR 53404 (August 26, 2011) (''*Initiation*''). The *Initiation* covered the following companies: (1) Pingdingshan Coal Group Kaifeng Xinghua Fine Chemical Plant (''Fine Chemical''); (2) Tianjin Changjie Chemical Co., Ltd. (''Changjie Chemical''); (3) Tianjin North Food Co., Ltd. (''North Food''); (4) Hangzhou Embaiking Pharmaceutical Corp. Ltd. (''Embaiking Pharmaceutical''); (5) Escalade Ltd./Escalade Israel Ltd. (''Escalade''); (6) The High Trans Corporation (''High Trans Corporation''); (7) The Seicheng Chemical Company (aka Sei Cheng) (''Seicheng Chemical''); (8) Yuan Shan Co. Ltd. (''Yuan Shan''); (9) Sin-Ho Trading Co. Ltd. (aka Xin He) (''Sin-Ho Trading''); (10) Long Hwang Chemicals Co. Ltd. (aka Lung Huang Trading) (''Long Hwang Chemicals''); (11) Sun Disc Company, Ltd. (''Sun Disc''); and (12) Kingchem.

[5] *See* Memorandum to the File, ''Saccharin from the People's Republic of China: Release of U.S. Entry Documents from the Department's August 25, 2011 Request—A–570–878,'' (''Release of Entry Data'') dated October 25, 2011.

[6] The Department's no-shipment inquiry is located on the CBP Web site under message number 1355309, dated December 21, 2011. *See http://addcvd.cbp.gov.*

Abstract Service (''CAS'') Registry 128–44–9); (2) calcium saccharin (CAS Registry 6485–34–3); (3) acid (or insoluble) saccharin (CAS Registry 81–07–2); and (4) research grade saccharin. Most of the U.S.-produced and imported grades of saccharin from the PRC are sodium and calcium saccharin, which are available in granular, powder, spray-dried powder, and liquid forms. The merchandise subject to this order is currently classifiable under subheading 2925.11.00 of the *Harmonized Tariff Schedule of the United States* (''HTSUS'') and includes all types of saccharin imported under this HTSUS subheading, including research and specialized grades. Although the HTSUS subheading is provided for convenience and customs purposes, the Department's written description of the scope of this order remains dispositive.

Intent To Rescind the Administrative Review in Part

19 CFR 351.213(d)(1) provides that the Department will rescind an administrative review if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review, or withdraws it at a later date if the Department determines it is reasonable to extend the time limit for withdrawing the request. The Department initiated this administrative review on August 26, 2011.[7] On August 30, 2011, Kinetic timely withdrew its request for review covering Kingchem in accordance with 19 CFR 351.213(d)(1). No other party requested a review of Kingchem. However, Kingchem does not have a separate rate but is part of the PRC-wide entity which continues to be under review. Therefore, the Department intends to rescind this review with respect to Kingchem at the final results of review.

The PRC-Wide Entity

Fine Chemical, Changjie Chemical, North Food, and Embaiking Pharmaceutical, all companies located in the PRC, did not submit separate rate applications or certifications to demonstrate their eligibility for separate rate status. As stated in the *Initiation,* ''[a]ll firms listed below that wish to qualify for separate-rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate-rate application or certification, as described below.'' [8] Because Fine Chemical, Changjie Chemical; North Food, and Embaiking Pharmaceutical did not demonstrate that they were entitled to a separate rate, the Department preliminarily finds that they should be considered part of the PRC-wide entity for this review.

Third-Country Exporters

CBP data reviewed by the Department do not show any reviewable entries of subject merchandise made by the third-country exporters Escalade, High Trans Corporation, Seicheng Chemical, Yuan Shan, Sin-Ho Trading, Long Hwang Chemicals, and Sun Disc during the POR. There is no information on the record of this proceeding indicating that the third-country exporters made entries of subject merchandise during the POR. Because these companies are located outside of the PRC, and they do not have individual exporter rates, the Department preliminarily determines that their entries of subject merchandise will be assessed at the rate applicable to their PRC suppliers.

Assessment Rates

If these preliminary results of review and intent to rescind are adopted in the final results, then antidumping duties will be assessed as follows. For all shipments of the subject merchandise by the PRC-wide entity entered, or withdrawn from warehouse, for consumption during the POR we intend to instruct CBP to assess antidumping duties at the *ad valorem* PRC-wide entity rate of 329.94 percent. For all non-PRC exporters of subject merchandise which have not received their own rate, we intend to instruct CBP to assess the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. The Department intends to issue assessment instructions directly to CBP 15 days after the publication of the final results in the **Federal Register.**

Cash Deposit Requirements

If these partial preliminary results are adopted in the final results, then the following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed PRC and non-PRC exporters that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide entity rate of 329.94 percent; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Since no calculations were performed for these partial preliminary results, no disclosure is required under 19 CFR 351.224(b). Any interested party may request a hearing within 30 days of publication of this notice in accordance with 19 CFR 351.310(c). Any hearing will be held 37 days after the publication of this notice, or the first business day thereafter unless the Department alters the date pursuant to 19 CFR 351.310(d). Individuals who wish to request a hearing must submit a written request within 30 days of the publication of this notice in the **Federal Register** to the Assistant Secretary for Import Administration, U.S. Department of Commerce, pursuant to the Department's e-filing regulations.[9] Requests for a public hearing should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) to the extent practicable, an identification of the arguments to be raised at the hearing.

Unless otherwise notified by the Department, interested parties may submit case briefs within 30 days of the date of publication of this notice in accordance with 19 CFR 351.309(c)(1)(ii). As part of the case brief, parties are encouraged to provide a summary of the arguments and a table of authorities cited in accordance with 19 CFR 351.309(c)(2). Rebuttal briefs, which must be limited to issues raised in the case briefs, must be filed within five days after the case brief is filed in accordance with 19 CFR 351.309(d). All briefs must be filed in accordance with the Department's e-filing regulations.[10] Parties should confirm by telephone the time, date, and place of the hearing within 48 hours before the scheduled time. The Department intends to issue the final results of this review, which will include the results of its analysis of issues raised in the briefs, not later than 120 days after the date of publication of this notice in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

[7] *See Initiation.*

[8] *See id.,* 76 FR at 53405.

[9] *See https://iaaccess.trade.gov/help/IA%20ACCESS%20User%20Guide.pdf.*

[10] *Id.*

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213(d)(4).

Dated: April 2, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2012–8866 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–957]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from an interested party, United States Steel Corporation, the Department of Commerce (the Department) initiated an administrative review of the countervailing duty order on seamless carbon and alloy steel standard, line, and pressure pipe from the People's Republic of China. The period of review is November 10, 2010, through December 31, 2010. Based on the timely withdrawal of the request for review submitted by United States Steel Corporation, we are now rescinding this administrative review.

DATES: *Effective Date:* April 12, 2012.

FOR FURTHER INFORMATION CONTACT: Patricia Tran or Eric Greynolds, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1503 or (202) 482–6071, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 30, 2011, the Department published in the **Federal Register** a notice of initiation of an administrative review of the countervailing duty order on seamless carbon and alloy steel standard, line, and pressure pipe from the People's Republic of China covering the period November 1, 2010, through December 31, 2010. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 76 FR 82268 (December 30, 2011). The review covers 32 companies.[1] United States Steel Corporation requested a review of all of those companies. No other party requested a review.

On March 29, 2012, and amended on April 3, 2012, United States Steel Corporation withdrew its request for an administrative review of the 32 companies.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review if the party that requested the review withdraws its request for review within 90 days of the publication of the notice of initiation of the requested review, or withdraws at a later date if the Department exercises its discretion to extend the time limit for withdrawing the request. United States Steel Corporation withdrew its request within the 90-day deadline. Therefore, we are rescinding the review with respect to all companies.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. Countervailing duties shall be assessed at rates equal to the cash deposit or bonding rate of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Notifications

This notice serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: April 5, 2012.

Edward C. Yang,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–8841 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–DS–P

[1] United Steel Corporation requested an administrative review on the following companies: Anhui Tianda Oil Pipe, Baoshan Iron & Steel Co., Ltd., Beijing Sai Lin Ke Hardware Co., Ltd., Hengyang Steel Tube Group Int'l Trading Inc., Hengyang Valin MPM Tube Co., Ltd., Hengyang Valin Steel Tube Co., Ltd., Hunan Valin Iron & Steel Group Co., Ltd., Hunan Valin Steel Co., Ltd., Hunan Valin Xiangtan Iron & Steel Co., Ltd., Jiangsu Changbao Steel Tube Co., Ltd., Jiangsu Chengde Steel Tube Share Company, Jiangsu Xigang Group Co., Ltd., Jiangyin City Changjiang Steel Pipe Co., Ltd., LDR Industries, Inc., Pangang Group Chengdu Iron & Steel Co., Shandong Luxing Steel Pipe, Shandong HuaBao Steel Pipe, Shanghai Tianyang Steel Tube, Tianguan Yuantong Pipe Product Co., Ltd., Tianjin Pipe (Group) Corporation, Tianjin Pipe International Economic & Trading Corp., Tianjin Pipe Iron Manufacturing Co., Ltd., TPCO Charging Development Co., Ltd., Wuxi Resources Steel Making Co., Ltd., Wuxi Seamless Special Pipe Co., Ltd., Wuxi Sifang Steel Tube Co., Ltd., Wuxi Zhenda Special Steel Tube Manufacturing, Xigang Seamless Steel Tube, Xuzhou Global Pipe and Fitting Mfg., Yangzhou Chengde Steel Tube Co., Ltd., Yangzhou Lontrin Steel Tube Co., Ltd., and Yantai Lubao Steel Tube.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–357–813]

Honey From Argentina: Rescission of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 12, 2012.

FOR FURTHER INFORMATION CONTACT: Toni Page, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1398.

SUPPLEMENTARY INFORMATION:

Background

On December 10, 2001, the Department of Commerce (Department) published in the **Federal Register** the countervailing duty order on honey from Argentina. *See Notice of Countervailing Duty Order: Honey From Argentina,* 66 FR 63673 (December 10, 2001). On December 1, 2011, the Department published a notice of opportunity to request an administrative review of the countervailing duty order on honey from Argentina for the period January 1, 2011, through December 31, 2011. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 76 FR 74773 (December 1, 2011). On January 3, 2012, in accordance with 19 CFR 351.213(b), the Department received a timely request from the American Honey Producers Association and the Sioux Honey Association (collectively, Petitioners), to conduct an administrative review. In accordance with section 751(a)(1) of the Tariff Act of 1930 (the Act) and 19 CFR 351.221(c)(1)(i), on January 31, 2012, the Department published a notice initiating an administrative review of the countervailing duty order. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 77 FR 4759 (January 31, 2012). On March 13, 2012, Petitioners withdrew their request for review.

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. Petitioners' March 13, 2012, withdrawal was filed within the 90-day period, and no other party requested a review. Therefore, pursuant to 19 CFR 351.213(d)(1), the Department is rescinding this administrative review.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties at the cash deposit rate in effect on the date of entry, for all entries of honey from Argentina during the period January 1, 2011, through December 31, 2011. The Department intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice of rescission of administrative review.

Notification Regarding Administrative Protective Order

This notice serves as a final reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: April 5, 2012.

Edward C. Yang,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–8840 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application 12–00001]

Export Trade Certificate of Review

ACTION: Notice of Application for an Export Trade Certificate of Review from Panama Poultry Export Quota, Inc.

SUMMARY: The Export Trading Company Affairs (''ETCA'') unit, Office of Competition and Economic Analysis, International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review (''Certificate''). This notice summarizes the conduct for which certification is sought and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Competition and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register**, identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked ''privileged'' or ''confidential business information'' will be deemed to be nonconfidential. An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Export Trading Company Affairs, International Trade Administration, U.S. Department of Commerce, Room 7021X, Washington, DC 20230, or transmitted by Email at *oetca@ita.doc.gov.* Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. § 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 12–00001.'' A summary of the application follows.

Summary of the Application

Applicant: Panama Poultry Export Quota, Inc. (''PAN–PEQ''), 1700 Pennsylvania Avenue NW., Suite 200, Washington, DC 20006.

Application No.: 12–00001.

Date Deemed Submitted: March 27, 2012.

Members (in addition to applicant): Panama Poultry Export Quota, Inc. members include the following entities: USA Poultry & Egg Export Council (USAPEEC''), 2300 West Park Place, Boulevard, Suite 200, Stone Mountain, Georgia 30087, and Associacion Nacional de Avicultores de Panama (''ANAVIP''), Calle 75, Manuel de Jesus Quijano, San Francisco, Casa No. 61, Apartado Postal 0819–06190, Panama, Republic of Panama.

PAN–PEQ seeks a Certificate of Review to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets:

Export Trade

Products

PAN–PEQ plans to export Chicken leg quarters, (or parts of chicken leg quarters, including legs or thighs), fresh, chilled or frozen, seasoned or unseasoned, marinated or not marinated, classifiable under HTS 0207.13.99, 0207.14.99 and 1602.32.00.

Export Markets

Chicken leg quarters for which awards will be made will be exported to the Republic of Panama.

1. *Purpose.* PAN–PEQ will manage on an open tender basis the tariff-rate quotas (TRQs) for poultry products granted by the Republic of Panama to the United States under the terms of the Panama Trade Promotion Agreement or any amended or successor agreement providing for Panamanian poultry TRQs for the United States of America. PAN–PEQ also will provide for distributions of the proceeds received from the tender process based on exports of poultry (''the TRQ System'') to support the operation and administration of PAN–PEQ and for the benefit of the poultry industries in the Republic of Panama and the United States.

2. *Implementation.*

A. *Administrator.* PAN–PEQ shall contract with a neutral third party Administrator who is not engaged in the production, sale, distribution or export of poultry or poultry products and who shall bear responsibility for administering the TRQ System, subject to general supervision and oversight by the Board of Directors of PAN–PEQ.

B. *Membership.* PAN–PEQ's members under this certificate are the USA Poultry and Egg Export Council (''USAPEEC'') on behalf of the U.S. poultry industry; and the Asociación Nacional de Avicultores de Panamá (''ANAVIP'') on behalf of the Panamanian poultry industry.

C. *Open Tender Process.* PAN–PEQ shall offer TRQ Certificates for duty-free shipments of chicken leg quarters to the Republic of Panama solely and exclusively through an open tender process with certificates awarded to the highest bidders (''TRQ Certificates''). PAN–PEQ shall hold tenders in accordance with tranches established in the relevant regulations of the Republic of Panama, or in the absence of such, at least once each year. The award of TRQ Certificates under the open tender process shall be determined solely by the Administrator in accordance with Section I without any participation by the Board of Directors.

D. *Persons or Entities Eligible to Bid.* Any person or entity incorporated or with a legal address in the United States of America shall be eligible to bid in the open tender process.

E. *Notice.* The Administrator shall publish notice (''Notice'') of each open tender process to be held to award TRQ Certificates in the *Journal of Commerce* and, at the discretion of the Administrator, in other publications of general circulation within the U.S. poultry industry or in the Republic of Panama. The Notice will invite independent bids and will specify (i) the total amount (in metric tons) that will be allocated pursuant to the applicable tender; (ii) the shipment period for which the TRQ Certificates will be valid; and (iii) the date and time by which all bids must be received by the Administrator in order to be considered (the ''Bid Date''); and (iv) a minimum bid amount per ton, as established by the Board of Directors, to ensure the costs of administering the auction are recovered. The Notice normally will be published not later than 30 business days prior to the first day of the shipment period and will specify a Bid Date that is at least 10 business days after the date of publication of the Notice. The Notice will specify the format for bid submissions. Bids must be received by the Administrator not later than 5 p.m. EST on the Bid Date.

F. *Contents of Bid.* The bid shall be in a format established by the Administrator and shall state (i) the name, address, telephone and facsimile numbers, and email address of the bidder; (ii) the quantity of poultry bid, in metric tons or portions of metric tons; (iii) the bid price in U.S. dollars per metric ton; and (iv) the total value of the bid. The bid form shall contain a provision, that must be signed by the bidder, agreeing that (i) any dispute that may arise relating to the bidding process or to the award to TRQ Certificates shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules; and (ii) judgment on any award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

G. *Performance Security.* The bidder shall submit with each bid a performance bond, irrevocable letter of credit drawn on a U.S. bank, cashier's check, wire transfer or equivalent security, in a form approved and for the benefit of an account designated by the Administrator, in the amount of $50,000 or the total value of the bid, whichever is less. The bidder shall forfeit such performance security if the bidder fails to pay for any TRQ Certificates awarded within five (5) business days. The bidder may chose to apply the performance security to the price of any successful bid, or to retain the performance security for a subsequent open tender process. Promptly after the close of the open tender process, the Administrator shall return any unused or non-forfeited security to the bidder.

H. *Confidentiality of Bids.* The Administrator shall treat all bids and their contents as confidential. The Administrator shall disclose information about bids only to: (a) An external auditor retained for purposes of auditing auction results and proceeds; (b) an authorized neutral third party, or, (c) an authorized government official of the United States or of the Republic of Panama, and only as necessary to ensure the effective operation of the TRQ System.

I. However, after the issuance of all TRQ Certificates from an open tender process, the Administrator shall notify all bidders and shall disclose publicly (i) the total tonnage for which TRQ Certificates were awarded, and (ii) the lowest price per metric ton of all successful bids.

J. *Award of TRQ Certificates.* The Administrator shall award TRQ Certificates for the available tonnage to the bidders who have submitted the highest price conforming bids. If two or more bidders have submitted bids with identical prices, the Administrator shall divide the remaining available tonnage in proportion to the quantities of their bids, and offer each TRQ Certificates in the resulting tonnages. If any bidder declines all or part of the tonnage offered, the Administrator shall offer that tonnage first to the other tying bidders, and then to the next highest bidder.

K. *Payment for TRQ Certificates.* Promptly after being notified of a TRQ award and within the time specified in the Notice, the bidder shall pay the full amount of the bid, either by wire transfer or by certified check, to an account designated by the Administrator. If the bidder fails to make payment within five (5) days, the Administrator shall revoke the award and award the tonnage to the next highest bidder(s).

L. *Delivery of TRQ Certificates.* The Administrator shall establish an account for each successful bidder in the amount of tonnage available for TRQ Certificates. Upon request, the Administrator will issue TRQ Certificates in the tonnage designated by the bidder, consistent with the balance in that account. The TRQ Certificate shall state the delivery period for which it is valid.

M. *Transferability.* TRQ Certificates shall be freely transferable except that (i) any TRQ Certificate holder who intends to sell, transfer or assign any rights under that Certificate shall publish such intention on a Web site maintained by the Administrator at least three (3) business days prior to any sale, transfer or assignment; and (ii) any TRQ holder that sells, transfers or assigns its rights under a TRQ Certificate shall provide the Administrator with notice and a copy of the sale, transfer or assignment within three (3) business days.

N. *Deposit of Proceeds:* The Administrator shall cause all proceeds of the open tender process to be deposited in an interest-bearing account in a financial institution approved by the PAN–PEQ Board of Directors.

O. *Disposition of Proceeds.* The proceeds of the open tender process shall be applied and distributed as follows:

i. The Administrator shall pay from tender proceeds, as they become available, all operating expenses of PAN–PEQ, including legal, accounting and administrative costs of establishing and operating the TRQ System, as authorized by the Board of Directors.

ii. Of the proceeds remaining at the end of each year of operations after all costs described in (i) above have been paid—

1. Fifty percent (50%) shall be distributed to fund export market development, educational, scientific and technical projects to benefit the United States poultry industry. PAN–PEQ shall accept proposals for the funding of projects approved by the Board of Directors of USAPEEC. The Administrator shall disburse funds to those projects approved for funding by the PAN–PEQ Board of Directors.

2. Fifty percent (50%) shall be distributed to fund market development, educational, scientific and technical projects to benefit the poultry industry of the Republic of Panama. PAN–PEQ shall accept proposals for funding of projects approved by the Board of Director of ANAVIP. The Administrator shall disburse funds to those projects approved for funding by the PAN–PEQ Board of Directors.

P. *Arbitration of Disputes.* Any dispute, controversy or claim arising out of or relating to the TRQ System or the breach thereof, including *inter alia,* a Member's qualification for distribution, interpretation of documents, or of the distribution itself, shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

Q. *Confidential Information.* The Administrator shall maintain as confidential all export documentation or other business sensitive information submitted in connection with application for PAN–PEQ membership, bidding in the open tender process or requests for distribution of proceeds, where such documents or information has been marked ''Confidential'' by the person making the submission. The Administrator shall disclose such information only to another neutral third party, or authorized government official of the United States or of the Republic of Panama, and only where necessary to ensure the effective operation of the TRQ System or where required by law (including appropriate disclosure in connection with the arbitration of a dispute).

R. *Annual Reports.* PAN–PEQ shall publish an annual report including a statement of its operating expenses and data on the distribution of proceeds, as reflected in the audited financial statement of the PAN–PEQ TRQ System.

Dated: April 5, 2012.

Joseph E. Flynn,

Director, Office of Competition and Economic Analysis.

[FR Doc. 2012–8759 Filed 4–11–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Applications and Reports for Registration as a Tanner or Agent

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before June 11, 2012.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Les Cockreham, (907) 271–3021 or *les.cockreham@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

The Marine Mammal Protection Act exempts Alaskan natives from the prohibitions on taking, killing, or injuring marine mammals if the taking is done for subsistence or for creating and selling authentic native articles of handicraft or clothing. The natives need no permit, but non-natives who wish to act as a tanner or agent for such native products must register with NOAA and maintain and submit certain records. The information is necessary for law enforcement purposes.

II. Method of Collection

Paper documentation is submitted to meet the requirements found at 50 CFR 216.23(c).

III. Data

OMB Control Number: 0648–0179.

Form Number: None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for profit organizations.

Estimated Number of Respondents: 53.

Estimated Time per Response: 2 hours for an application and 2 hours for a report.

Estimated Total Annual Burden Hours: 106.

Estimated Total Annual Cost to Public: $53 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 6, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–8791 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XB135

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Highly Migratory Species Management Team (HMSMT) will hold a work session which is open to the public.

DATES: The meeting will be held Monday, April 30th through Wednesday, May 2, 2012. The HMSMT work session will begin at 1 p.m. on Monday, April 30 and at 8:30 a.m. on the following days, and continue until business is completed on each day.

ADDRESSES: The work sessions will be held at Large Conference Room, Pacific Fishery Management Council Office, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Dr. Kit Dahl, Pacific Fishery Management Council; telephone: (503) 820–2280.

SUPPLEMENTARY INFORMATION: The HMSMT will discuss further development of information to support Council recommendations on an international management framework for North Pacific albacore tuna. The HMSMT presented information to the Council at its March 2012 meeting and the Council requested additional information to support discussion at its June 21–26, 2012, meeting in San Mateo, CA. The HMSMST may also discuss work planning and future assignments.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2280 at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 9, 2012.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2012–8805 Filed 4–11–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Regents of the Uniformed Services University of the Health Sciences; Quarterly Meeting Notice

AGENCY: Uniformed Services University of the Health Sciences (USU), Department of Defense.

ACTION: Quarterly meeting notice.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended) and the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended), this notice announces the following meeting of the Board of Regents of the Uniformed Services University of the Health Sciences.

DATES: Friday, May 18, 2012, from 8 a.m. to 1:30 p.m. (Open Session) and 1:30 p.m. to 3 p.m. (Closed Session).

ADDRESSES: Everett Alvarez Jr. Board of Regents Room (D3001), Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Janet S. Taylor, Designated Federal Officer, 4301 Jones Bridge Road, Bethesda, Maryland 20814; telephone 301–295–3066. Ms. Taylor can also provide base access procedures.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: Meetings of the Board of Regents assure that USU operates in the best traditions of academia. An outside Board is necessary for institutional accreditation.

Agenda: The actions that will take place include the approval of minutes from the Board of Regents Meeting held February 7, 2012; recommendations regarding the approval of faculty appointments and promotions in the School of Medicine and the Postgraduate Dental College; and recommendations regarding the awarding of post-baccalaureate degrees as follows: Doctor of Medicine, Ph.D. in Nursing Science, Master of Science in Nursing, Master of Science in Oral Biology, and master's and doctoral degrees in the biomedical sciences and public health. The President, USU and the President and CEO, Henry M. Jackson Foundation for the Advancement of Military Medicine will present reports and Regents will also receive information from both academic and administrative University officials. These actions are necessary for the University to pursue its mission, which is to provide outstanding health care practitioners and scientists to the uniformed services.

Meeting Accessibility: Pursuant to Federal statute and regulations (5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165) and the availability of space, most of the meeting is open to the public. Seating is on a first-come basis. Members of the public wishing to attend the meeting should contact Janet S. Taylor at the address and phone number in **FOR FURTHER INFORMATION CONTACT**. The closed portion of this meeting is authorized by 5 U.S.C. 552b(c)(6) as the subject matter involves personal and private observations.

Written Statements: Interested persons may submit a written statement for consideration by the Board of Regents. Individuals submitting a written statement must submit their statement to the Designated Federal Officer at the address listed in **FOR FURTHER INFORMATION CONTACT**. If such statement is not received at least 10 calendar days prior to the meeting, it may not be provided to or considered by the Board of Regents until its next open meeting. The Designated Federal Officer will review all timely submissions with the Board of Regents Chairman and ensure such submissions are provided to Board of Regents Members before the meeting. After reviewing the written comments, submitters may be invited to orally present their issues during the May 2012 meeting or at a future meeting.

Dated: April 9, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–8843 Filed 4–11–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2012–OS–0046]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Office of the Secretary of Defense proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on May 14, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Allard, Chief, OSD/JS Privacy Office, Freedom of Information Directorate, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155, or by phone at (571) 372–0461.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 9, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DSCA 02

SYSTEM NAME:

Regional International Outreach System (March 7, 2007, 72 FR 10180).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''GlobalNET Outreach and Collaboration Platform''.

SYSTEM LOCATION:

Delete entry and replace with ''Amazon Web Services, LLC 13461 Sunrise Valley Drive, Herndon, VA 20171–3283.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''DoD Military and civilian employees, U.S. military students, alumni, contractors, systems integrators, and subject matter experts who interact with DoD educational institutions.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Name, citizenship, home and email addresses, personal telephone numbers, gender, date of birth, month/year of attendance and course subjects, and biographic information such as subject matter expertise, background, and education.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 134, Under Secretary of Defense for Policy; DoD Directive 5105.65, Defense Security Cooperation Agency (DSCA), Section 5.10; DoD Directive 5101.1, DoD Executive Agent, Section 5.2.7; DoD Directive 5200.41, DoD Centers for Regional Security Studies, Section 3.1; and DoD Directive 5132.03, DoD Policy and Responsibilities Relating to Security Cooperation.''

PURPOSE(S):

Delete entry and replace with ''To improve collaboration and outreach efforts (with students, graduates and subject matter experts) among the DoD Regional Centers for Security Studies, and additional organizations/communities, as directed.''

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''Name, email address, subject matter expertise, month/year of attendance, and course subject.''

SAFEGUARDS:

Delete entry and replace with ''Access is limited to those individuals with a need to know in order to perform official and assigned duties. Physical access is limited through the use of locks, guards, card swipe, and other administrative procedures. The electronic records are housed on systems with access restricted by the use of login, password, and/or card swipe protocols. Users are warned through screen log-on, protocols and/or in briefings of the consequences of improper access or use of the data. The web-based files are encrypted in accordance with approved information assurance protocols. The user can also restrict access to his personal data by selecting which type of information is available to members, friends, or others.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Disposition pending (until the National Archives and Records Administration approve the retention and disposition of these records, treat as permanent).''

SYSTEM MANAGER AND ADDRESS:

Delete entry and replace with ''GlobalNET Program Manager, Defense Security Cooperation Agency, ATTN: PGM/CMO, 201 12th Street S, Suite 203, Arlington, VA 22202–5408.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to GlobalNET Program Manager, the Defense Security Cooperation Agency, ATTN: PGM/CMO, 201 12th Street S, Suite 203, Arlington, VA 22202–5408.

Written requests should contain the full name, home and/or email addresses, telephone number, and organization.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to records about themselves contained in this system should address written inquiries to the Office of the Secretary of Defense/Joint Staff Freedom of Information Act Requester Service Center, 1155 Defense Pentagon, Washington DC 20301–1155.

Written requests should contain the full name, home and/or email addresses, telephone number, and organization, the name and number of this system of records notice and be signed.''

* * * * *

[FR Doc. 2012–8833 Filed 4–11–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0043]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Intelligence Agency proposes to alter a system in its existing inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on May 14, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery at Defense Intelligence Agency, DAN 1–C, 600 McDill Boulevard, Washington, DC 20340–0001, or by phone at (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 9, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

LDIA 05–0003

SYSTEM NAME: JOINT INTELLIGENCE VIRTUAL UNIVERSITY (JIVU II) (MARCH 24, 2008, 73 FR 15496)

CHANGES:

* * * * *

SYSTEM LOCATIONS:

Delete entry and replace with ''Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–0001.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Federal employees, contractors and active duty service members who access the Joint Intelligence Virtual University (JIVU II) in order to facilitate a training requirement.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''All records in this system of records contain identifying information: Name, Social Security Number (SSN), Employee Identification Number (EIN), email address and organization. Records include training and education material on subject individuals that are necessary to achieve Agency and Intelligence Community missions.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. Chapter 41, Training; E.O. 11348, Training and Development Policy, as amended; DoDI 3305.2, DoD General Intelligence Training; DIA 1025.200, Training of Defense Intelligence Personnel; and E.O. 9397 (SSN), as amended.''

PURPOSE(S):

Delete entry and replace with ''The purpose of this system is to ensure Federal employees, contractors and active duty service members attain the knowledge and skills necessary to achieve Agency and Intelligence Community missions through a Web-based training environment and to link such training to the user's personnel records.''

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''By last name, EIN or SSN.''

SAFEGUARDS:

Delete entry and replace with ''Records are stored in office buildings protected by guards, controlled screenings, use of visitor registers, electronic access, and/or locks. Access to records is limited to individuals who are properly screened and cleared on a need-to-know basis in the performance of their duties. Passwords and User IDs are used to control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access are limited to persons responsible for servicing and authorized to use the system.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Temporary records-destroy when 5 years old or when superseded or obsolete, whichever is sooner. Electronic records are deleted from the system.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Function Lead, Joint Virtual Intelligence University (JIVU), Directorate for Human Capital, Defense Intelligence Agency, 200 MacDill Boulevard, Washington, DC 20340–0001.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the DIA Freedom of Information Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–0001.

Request should contain the individual's full name, current address, and telephone number.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves, contained in this system of records, should address written inquiries to the DIA Freedom of Information Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Boulevard, Washington, DC 20340–0001.

Request should contain the individual's full name, current address, and telephone number.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''DIA's rules for accessing records, for contesting contents and appealing initial agency determinations are published in DIA Instruction 5400.001 ''Defense Intelligence Agency Privacy Program''; or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Agency officials, employees, educational institutions, military organizations and other Government officials.''

* * * * *

[FR Doc. 2012–8836 Filed 4–11–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0045]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Defense Intelligence Agency is proposing to add a system to its existing inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on May 14, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery at Defense Intelligence Agency, DAN 1–C, 600 MacDill Blvd., Washington, DC 20340–0001 or by phone at (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency system of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 9, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

LDIA 12–0001

SYSTEM NAME:

Unique Identifying Number (UIN) Management Records.

SYSTEM LOCATION:

Defense Intelligence Agency, 200 MacDill Blvd. Washington, DC 20340

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department of Defense (DoD) current and former civilian, military and affiliate personnel, non DoD and other U.S. Government agency personnel, interagency mobile interrogation teams, foreign government personnel, and DoD and non-DoD law enforcement counterintelligence personnel who conduct or support strategic intelligence interrogations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Unique Indentifying Number (UIN), name, Social Security Number (SSN), status or affiliation, current location and contact information, and information relating to individuals or team functions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1080 of Public Law 111–84, The National Defense Authorization Act; DoD 3115.09, DoD Intelligence Interrogations, Detainee Debriefings and Tactical Questioning; DoD 5240.1–R, Procedures Governing the Activities of DoD Intelligence Components that Affect United States Persons; and E.O. 9397, as amended.

PURPOSE(S):

Manages the identification of strategic interrogation and support personnel and their employing U.S. Government agency or affiliate through assignment of a Unique Identifying Number (UIN).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records contained therein may specifically be disclosed outside of DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of the DIA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage media.

RETRIEVABILITY:

Unique Indentifying Number (UIN), name and Social Security Number (SSN).

SAFEGUARDS:

Records are stored in secure office buildings protected by guards, controlled screenings, use of visitor registers, electronic access, and/or locks. Access to records is limited to individuals who are properly screened and cleared on a need-to-know basis in the performance of their duties. Passwords and User IDs are used to control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access is limited to persons responsible for servicing and authorized to use the system.

RETENTION AND DISPOSAL:

TEMPORARY. Delete upon incorporation into final communication, report or other action.

SYSTEM MANAGER AND ADDRESSES:

Program Manager, Defense Source Registry, Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–0001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the DIA Freedom of Information Act Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100.

Request should contain the individual's full name, current address and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves, contained in this system of records, should address written inquiries to the DIA Freedom of Information Act Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100.

Requests should contain the requesting individual's full name, current address, and telephone number.

CONTESTING RECORD PROCEDURES:

DIA's rules for accessing records, for contesting contents and for appealing initial agency determinations are published in DIA Instruction 5400.001, Defense Intelligence Agency Privacy Program, or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals provide information and the Program Manager assigns the unique identifying number.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2012–8834 Filed 4–11–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0044]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Intelligence Agency proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective further notice on May 14, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery at Defense Intelligence Agency, DAN 1–C, 600 MacDill Boulevard, Washington, DC 20340–0001, or by phone at (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency system of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 6, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 9, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

LDIA 0435

DIA Military Awards Files (March 18, 2010, 75 FR 13089)

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''DIA Military Recognition and Awards Files.''

SYSTEM LOCATION:

Delete entry and replace with ''Defense Intelligence Agency, 200 MacDill Boulevard, Washington, DC 20340–0001.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Military personnel recommended for recognition or awards while assigned or attached to DIA.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Full name, rank, service affiliation, and Social Security Number (SSN) of individual, supporting documents for the awards nomination and the results of actions or recommendations of endorsing and approving officials for recognition and awards.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 1125, Recognition for Accomplishments: award of trophies; Department of Defense Manual 1348.33, Volumes 1, 2, 3, Manual of Military Decorations; Defense Intelligence Agency Instruction 1348.001, Military Personnel Awards; Defense Intelligence Agency Instruction 1305.001, Military Quarterly and Annual Recognition Program; Army Regulation 600–8–22, Military Awards; SECNAV Inst 1650.1H, Navy and Military Awards Instruction; Air Force Instruction 36–2803, Air Force Awards and Decorations Program; and E.O. 9397 (SSN), as amended.''

PURPOSE(S):

Delete entry and replace with ''Information is collected and submitted to determine eligibility for recognition, awards, and decorations to individuals and units while assigned or attached to the DIA. Information is required for preparation of orders for award citation and inclusion in individual's Service record. Records are used to obtain the approval for the awarding of the decoration, for the compilation of required statistical data and provided to the Military departments when appropriate.''

* * * * *

STORAGE:

Delete entry and replace with ''Paper and electronic storage media.''

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with ''Temporary Records: Award citations and accompanying records are maintained for 3 years then retired to the Washington National Records Center where they are destroyed when 15 years old. The records are destroyed by shredding/erasure. Justification for the award records are maintained for 3 years within DIA and then destroyed by shredding or deleting from database.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Deputy Director for Human Capital, ATTN: Military Awards, Defense Intelligence Agency, 200 MacDill Boulevard, Washington, DC 20340–0001.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Freedom of Information Act Office (DAN–1A/FOIA), Defense Intelligence Agency, 200 MacDill Boulevard, Washington, DC 20340–0001.

The individual should provide their full name, current address, and telephone number.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the Freedom of Information Act Office (DAN–1A/FOIA), Defense Intelligence Agency, 200 MacDill Boulevard, Washington, DC 20340–0001.

The individual should provide their full name, current address, and telephone number.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''DIA's rules for accessing records, for contesting contents and appealing initial agency determinations are published in DIA Instruction 5400–001 Defense Intelligence Agency Privacy Program; 32 CFR part 319 or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Individuals, Agency officials, parent service and personnel records.''

* * * * *

[FR Doc. 2012–8835 Filed 4–11–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board Summer Study Meeting

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (U.S.C. 552b, as amended) and 41 Code of the Federal Regulations (CFR 102–3.140 through 160, the Department of the Army announces the following committee meeting:

Name of Committee: Army Science Board (ASB).

Date(s) of Meeting: May 3, 2012.

Time(s) of Meeting: 11 a.m. to 12 p.m.

Location: Capital Conference Center, 3601 Wilson BLVD, Arlington, VA 22201.

Purpose: Hear the preliminary findings of the *Strategic Directions for Army Science and Technology* and vote on adoption.

Proposed Agenda: Open Session, the ASB will hear preliminary findings of the Strategic Directions for Army Science & Technology study and vote on adoption.

FOR FURTHER INFORMATION CONTACT: Non ASB attendee's must contact Mr. Oscar Valent at 703–617–0316, *Oscar.B.Valent.ctr@mail.mil* before April 26, 2012 in order to attend.

SUPPLEMENTARY INFORMATION: None.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2012–8828 Filed 4–11–12; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13305–002]

Whitestone Power and Communications; Notice Concluding Pre-Filing Process and Approving Process Plan and Schedule

a. *Type of Filing:* Notice of Intent To File an Application for a Hydrokinetic Pilot Project License.

b. *Project No.:* 13305–002.

c. *Date Filed:* August 22, 2011.

d. *Submitted By:* Whitestone Power and Communications (Whitestone).

e. *Name of Project:* Microturbine Hydrokinetic River-In-Stream Energy Conversion Power Project.

f. *Location:* On the Tanana River near Delta Junction, Alaska. The project would not occupy any federal lands.

g. *Filed Pursuant to:* 18 CFR 5.3 and 5.5 of the Commission's regulations.

h. *Applicant Contact:* Steven M. Selvaggio, Whitestone Power and Communications, P.O. Box 1630, Delta Junction, Alaska 99737; (907) 895–4938.

i. *FERC Contact:* Dianne Rodman; (202) 502–6077.

j. *Whitestone has filed with the Commission:* (1) A notice of intent (NOI) to file an application for a pilot hydrokinetic hydropower project and a draft license application with monitoring plan; (2) a request for waiver of certain Integrated Licensing Process (ILP) regulations necessary for expedited processing of a license application for a hydrokinetic pilot project; (3) a proposed process plan and schedule; and (4) a request to be designated as the non-federal representative for section 7 of the Endangered Species Act (ESA) consultation and for section 106 consultation under the National Historic Preservation Act.

k. A notice was issued on August 25, 2011, soliciting comments on the draft license application from agencies and stakeholders. Comments were filed by the Alaska Department of Fish and Game.

l. Whitestone was designated as the non-federal representative for section 7 of the Endangered Species Act consultation and for section 106 consultation under the National Historic Preservation Act on January 21, 2011.

m. *The proposed Microturbine Hydrokinetic River-In-Stream Energy Conversion Power Project would consist of:* (1) A 12-foot-wide, 16-foot-diameter Poncelet undershot water wheel; (2) a 34-foot-long, 19- to 24-foot-wide aluminum-frame floatation platform mounted on a 34-foot-long, 3.5-foot-diameter high-density- polyethylene (HDPE) pontoon and a 34-foot-long, 3-foot-diameter HDPE pontoon; (3) a 100-kilowatt turbine/generator unit; (4) a 33-foot-long, 3.5-foot-wide gangway from the shore to the floating pontoon; (5) three anchoring cables to secure the flotation platform to the shore, including a 30-foot-long primary safety tether, a 117-foot-long primary cable, and a 100-foot-long secondary cable; (6) an approximately 900-foot-long transmission cable from the floatation platform to an existing Golden Valley Electric Association distribution line; and (7) appurtenant facilities. The project is anticipated to operate from April until October, with an estimated annual generation of 200 megawatt-hours.

n. The pre-filing process has been concluded and the requisite regulations have been waived such that the process and schedule indicated below can be implemented.

o. Post-filing process schedule. The post-filing process will be conducted pursuant to the following schedule. Revisions to the schedule may be made as needed.

Milestones	Dates
Final license application expected	April 17, 2012.
Issue notice of acceptance and ready for environmental analysis and request for interventions	May 2, 2012.

Milestones	Dates
Recommendations, Conditions, Comments and Interventions due	June 1, 2012.
Issue notice of availability of environmental assessment	July 31, 2012.
Comments due and 10(j) resolution, if needed	August 30, 2012.

p. Register online at *http://ferc.gov/esubscribenow.htm* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: April 5, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–8819 Filed 4–11–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR12–21–000]

MGTC, Inc.; Notice of Petition for Rate Approval

Take notice that on April 4, 2012, MGTC, Inc. (MGTC) filed a Rate Election pursuant to 284.123(b)(1) of the Commission's regulations and to revise its Statement of Operating Conditions. MGTC proposes to utilize rates that are the same as those contained in MGTC's transportation rate schedules for comparable intrastate service on file with the Wyoming Public Service Commission as more fully detailed in the petition.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on Monday, April 16, 2012.

Dated: April 6, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–8815 Filed 4–11–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD12–3–019]

Review of Cost Submittals by Other Federal Agencies for Administering Part I of the Federal Power Act; Notice Requesting Questions and Comments on Fiscal Year 2011 Other Federal Agency Cost Submissions

In its *Order On Rehearing Consolidating Administrative Annual Charges Bill Appeals And Modifying Annual Charges Billing Procedures,* 109 FERC ¶ 61,040 (2004) (October 8 Order) the Commission set forth an annual process for Other Federal Agencies (OFAs) to submit their costs related to Administering Part I of the Federal Power Act. Pursuant to the established process, the Director of the Financial Management Division, Office of the Executive Director, on October 19, 2011, issued a letter requesting the OFAs to submit their costs by January 17, 2012 using the OFA Cost Submission Form.

Upon receipt of the agency submissions, the Commission posted the information in eLibrary, and issued, on February 29, 2012, a notice announcing the date for a technical conference to review the submitted costs. On March 22, 2012, the Commission held the technical conference. Technical conference transcripts, submitted cost forms, and detailed supporting documents are all available for review under Docket No. AD12–3. These documents are accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and are available for review in the Commission's Public Reference Room in Washington, DC.

Interested parties may file specific questions and comments on the FY 2011 OFA cost submissions with the Commission under Docket No. AD12–3–019, no later than May 5, 2012. Once filed, the Commission will forward the questions and comments to the OFAs for response.

Anyone with questions pertaining to the technical conference or this notice should contact W. Doug Foster at (202) 502–6118 (via email at *doug.foster@ferc.gov*), or Fannie Kingsberry at (202) 502–6108 (via email at *fannie.kingsberry@ferc.gov*).

Dated: April 5, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–8816 Filed 4–11–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meeting. Their attendance is part of the Commission's ongoing outreach efforts.

Order No. 1000 Interregional Coordination Meeting

April 12, 2012

8:30 a.m.–3 p.m. (local time).

The above-referenced meeting will be held at: Renaissance Oklahoma City, 10 North Broadway Avenue, Oklahoma City, Oklahoma 73102.

The above-referenced meeting is open to the public.

Further information may be found at *www.misoenergy.org* or *www.spp.org.*

The discussions at the meeting described above may address matters at issue in the following proceedings:

Docket No. EL12–24	Pioneer Transmission LLC.
Docket No. EL12–28	Xcel Energy.
Docket No. ER12–1357	Louisville Gas and Electric Company.
Docket No. ER12–715	Midwest Independent Transmission System Operator, Inc.
Docket No. ER12–480	Midwest Independent Transmission System Operator, Inc.
Docket No. ER12–309	Midwest Independent Transmission System Operator, Inc.
Docket No. ER11–1844	Midwest Independent Transmission System Operator, Inc.
Docket No. EL11–56	FirstEnergy Service Company.
Docket No. EL11–30	*E.ON Climate & Renewables North America, LLC* v. *Midwest Independent Transmission System Operator, Inc.*
Docket No. OA08–53	Midwest Independent Transmission System Operator, Inc.
Docket No. ER09–35	Tallgrass Transmission, LLC.
Docket No. ER09–36	Prairie Wind Transmission, LLC.
Docket No. ER09–548	ITC Great Plains, LLC.
Docket No. ER11–4105	Southwest Power Pool, Inc.
Docket No. EL11–34	Midwest Independent Transmission System Operator, Inc.
Docket No. ER11–3967	Southwest Power Pool, Inc.
Docket No. ER11–3967	Southwest Power Pool, Inc.
Docket No. ER12–1179	Southwest Power Pool, Inc.
Docket No. OA07–32	Entergy Services, Inc.
Docket No. EL00–66	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL01–88	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL07–52	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–51	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–60	*Ameren Services Co.* v. *Entergy Services, Inc.*
Docket No. EL09–43	*Arkansas Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–50	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–61	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–55	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–65	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL11–34	Midwest Independent System Transmission Operator, Inc.
Docket No. ER05–1065	Entergy Services, Inc.
Docket No. ER07–682	Entergy Services, Inc.
Docket No. ER07–956	Entergy Services, Inc.
Docket No. ER08–1056	Entergy Services, Inc.
Docket No. ER09–833	Entergy Services, Inc.
Docket No. ER09–1224	Entergy Services, Inc.
Docket No. ER10–794	Entergy Services, Inc.
Docket No. ER10–1350	Entergy Services, Inc.
Docket No. ER10–1676	Entergy Services, Inc.
Docket No. ER10–2001	Entergy Arkansas, Inc.
Docket No. ER10–3357	Entergy Arkansas, Inc.
Docket No. ER11–2131	Entergy Arkansas, Inc.
Docket No. ER11–2132	Entergy Gulf States, Louisiana, LLC
Docket No. ER11–2133	Entergy Gulf States, Louisiana, LLC
Docket No. ER11–2134	Entergy Mississippi, Inc.
Docket No. ER11–2135	Entergy New Orleans, Inc.
Docket No. ER11–2136	Entergy Texas, Inc.
Docket No. ER11–3156	Entergy Arkansas, Inc.
Docket No. ER11–3657	Entergy Arkansas, Inc.
Docket No. ER12–480	Midwest Independent Transmission System Operator, Inc.

For more information, contact Zeny Magos, Office of Energy Markets Regulation, Federal Energy Regulatory Commission at (202) 502–8244 or *zeny.magos@ferc.gov.*

Dated: April 5, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–8817 Filed 4–11–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Attendance at the Entergy Regional State Committee Working Group and Stakeholder Meeting

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meeting noted below. Their attendance is part of the Commission's ongoing outreach efforts.

Entergy Regional State Committee Working Group and Stakeholder Meeting

April 17, 2012 (9 a.m.–3 p.m.)

This meeting will be held at the Pan American Life Center, 601 Poydras Street, New Orleans, LA 70130.

The discussions may address matters at issue in the following proceedings:

Docket No. OA07–32	Entergy Services, Inc.
Docket No. EL00–66	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL01–88	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*

Docket No. EL07–52	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–51	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–60	*Ameren Services Co.* v. *Entergy Services, Inc.*
Docket No. EL09–43	*Arkansas Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–50	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–61	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–55	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–65	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL11–34	Midwest Independent System Transmission Operator, Inc.
Docket No. EL11–63	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. ER05–1065	Entergy Services, Inc.
Docket No. ER07–682	Entergy Services, Inc.
Docket No. ER07–956	Entergy Services, Inc.
Docket No. ER08–1056	Entergy Services, Inc.
Docket No. ER09–833	Entergy Services, Inc.
Docket No. ER09–1224	Entergy Services, Inc.
Docket No. ER10–794	Entergy Services, Inc.
Docket No. ER10–1350	Entergy Services, Inc.
Docket No. ER10–1676	Entergy Services, Inc.
Docket No. ER10–2001	Entergy Arkansas, Inc.
Docket No. ER10–3357	Entergy Arkansas, Inc.
Docket No. ER11–2131	Entergy Arkansas, Inc.
Docket No. ER11–2132	Entergy Gulf States, Louisiana, LLC.
Docket No. ER11–2133	Entergy Gulf States, Louisiana, LLC.
Docket No. ER11–2134	Entergy Mississippi, Inc.
Docket No. ER11–2135	Entergy New Orleans, Inc.
Docket No. ER11–2136	Entergy Texas, Inc.
Docket No. ER11–3156	Entergy Arkansas, Inc.
Docket No. ER11–3657	Entergy Arkansas, Inc.
Docket No. ER12–480	Midwest Independent Transmission System Operator, Inc.

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

Dated: April 5, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–8818 Filed 4–11–12; 8:45 am]

BILLING CODE 6717–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Existing Collection; Reinstatement

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of Information Collection—Reinstatement Without Change: Elementary-Secondary Staff Information Report (EEO–5).

SUMMARY: In accordance with the Paperwork Reduction Act, the Equal Employment Opportunity Commission (EEOC or Commission) announces that it submitted to the Office of Management and Budget (OMB) a request for a Reinstatement Without Change of the Elementary-Secondary Staff Information Report (EEO–5).

FOR FURTHER INFORMATION CONTACT: Ronald Edwards, Director, Program Research and Surveys Division, 131 M Street NE., Room 4SW30F, Washington, DC 20507; (202) 663–4958 (voice) or (202) 663–7063 (TTY).

SUPPLEMENTARY INFORMATION: Elementary and secondary public school systems and districts have been required to submit EEO–5 reports to EEOC since 1974 (biennially in even-numbered years since 1982). Since 1996, each public school district or system has submitted all of the district data on a single form, EEOC Form 168A. The individual school form, EEOC Form 168B, was eliminated in 1996, reducing the respondent burden and cost.

Overview of Information Collection

Collection Title: Elementary-Secondary Staff Information Report (EEO–5).

OMB Number: 3046–0003.

Frequency of Report: Biennial.

Type of Respondent: Certain public elementary and secondary school districts.

Description of Affected Public: Certain public elementary and secondary school districts.

Number of Responses: 7,218.

Reporting Hours: 32,481.

Cost to the Respondents: $617,139.

Federal Cost: $190,000.

Number of Forms: 1.

Form Number: EEOC Form 168A.

Abstract: Section 709(c) of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–8(c), requires employers to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed, to preserve such records, and to produce reports as the Commission prescribes by regulation or order. Accordingly, the EEOC issued regulations prescribing the reporting requirements for elementary and secondary public school districts. The EEOC uses EEO–5 data to investigate charges of employment discrimination against elementary and secondary public school districts. The data also are used for research. The data are shared with the Department of Education (Office for Civil Rights) and the Department of Justice. Pursuant to Section 709(d) of Title VII of the Civil Rights Act of 1964, as amended, EEO–5 data also are shared with state and local Fair Employment Practices Agencies (FEPAs).

Burden Statement: The estimated number of respondents included in the biennial EEO–5 survey is 7,218 public elementary and secondary school districts. The form is estimated to impose 32,481 burden hours biennially.

Dated: April 4, 2012.

For the Commission.

Jacqueline A. Berrien,

Chair.

[FR Doc. 2012–8812 Filed 4–11–12; 8:45 am]

BILLING CODE 6750–01–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application for a $19.5 million long-term guarantee to support the export of approximately $30 million worth of mining trucks to the Ukraine. The repayment term of the guarantee is 7 years. The U.S. exports will enable the Ukrainian mining company to establish a maximum production capacity of 28 million metric tons of iron ore per year. Available information indicates that all of the Ukrainian iron ore production will be sold domestically in the Ukraine. Interested parties may submit comments on this transaction by email to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue NW., Room 947, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Angela Mariana Freyre,

Senior Vice President and General Counsel.

[FR Doc. 2012–8829 Filed 4–11–12; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 12–02]

Maher Terminal, LLC v. *The Port Authority of New York and New Jersey;* Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission'' by Maher Terminal, LLC, hereinafter ''Complainant'' against the Port Authority of New York and New Jersey (PANYNJ), hereinafter ''Respondent''. Complainant asserts that it is a limited liability company registered in the State of Delaware with corporate offices and facilities located in Elizabeth, New Jersey. Complainant asserts that Respondent, PANYNJ, is a body corporate and politic created by Compact between the States of New York and New Jersey and with the consent of the Congress; has offices located in New York, New York; owns marine terminal facilities in the New York New Jersey area, including in Elizabeth, New Jersey; and is a marine terminal operator.

Complainant contends that Respondent violated 46 U.S.C. 41102(c), 41106(2), 41106(3) and 41106(1) respectively, because Respondent:

(a) has and continues to fail to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing or delivery property; (b) gave and continues to give an undue or unreasonable prejudice or disadvantage with respect to Maher and gave and continues to give an undue or unreasonable preference or advantage with respect to Maersk, APM, MSC, PNCT, NYCT, and Global, and other marine container terminal operators and ocean carriers; (c) has and continues to unreasonably refuse to deal or negotiate with Maher; and (d) has and continues to agree with another marine terminal operator or common carrier to boycott and/or unreasonably discriminate in the provision of terminal services to a common carrier.

Complainant asserts that it has sustained injuries and damages, as a result of Respondent's actions, ''including but not limited to higher costs and other undue and unreasonable payments, economic considerations, restrictions on transfers and/or changes in ownership or control interests, lost business, forgone business, and additional obligations not required of * * * other marine terminals and other damages amounting to a sum of millions of dollars* * *'' The full text of the complaint can be found in the Commission's Electronic Reading Room at *www.fmc.gov.*

Complainant requests that the Commission require Respondent to: (1) Answer he charges in the subject complaint; (2) cease and desist from the aforementioned violations of the Shipping Act; (3) provide to Complainant the preferences provided to other marine terminal operators; (4) put in force such practices and as the Commission determines to be lawful and reasonable; and (5) pay to Complainant by way of reparations the amount of the actual injury, plus interest, cost and attorneys fees, and any other damages to be determined. Additionally, Complainant requests that the Commission order any such other relief as it determines appropriate.

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by April 8, 2013, and the final decision of the Commission shall be issued by August 6, 2013.

Karen V. Gregory,

Secretary.

[FR Doc. 2012–8777 Filed 4–11–12; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 7, 2012.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204:

1. *Coastway Bancorp, MHC and Coastway Bancorp, LLC,* both in Cranston, Rhode Island; to become a mutual bank holding company and a stock bank holding company, respectively, by acquiring 100 percent of the voting shares of Coastway

Community Bank, Cranston, Rhode Island.

B. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Cadence Bancorp, LLC,* Houston, Texas; to acquire 100 percent of the voting shares of Encore Bancshares, Inc., and thereby indirectly acquire Encore Bank, N.A., both in Houston, Texas.

Board of Governors of the Federal Reserve System, April 9, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–8832 Filed 4–11–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 23, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 202439/S–002, XARELTO (rivaroxaban), submitted by Janssen Pharmaceuticals, Inc., to reduce the risk of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) [ST elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), or unstable angina (UA)] in combination with aspirin alone or with aspirin plus clopidogrel or ticlopidine.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 9, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 1, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 2, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 9, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–8824 Filed 4–11–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representative on the Blood Products Advisory Committee, and Request for Nominations for Nonvoting Industry Representatives on the Blood Products Advisory Committee

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Blood Products Advisory Committee for the Center for Biologics Evaluation and Research (CBER) notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to serve on the Blood Products Advisory Committee. A nominee may either be self-nominated

or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by May 14, 2012, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by May 14, 2012.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Bryan Emery (see: **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Bryan Emery, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike (HFM–71), Rockville, MD 20852–1448, 301–827–1277, Fax: 301–827–0294, email: *bryan.emery@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative to the following advisory committee:

I. Blood Products Advisory Committee for the Center for Biologics Evaluation and Research

Members are selected by the Commissioner of Food and Drugs (the Commissioner) or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the blood and blood products manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 9, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–8823 Filed 4–11–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Notification of Intent To Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930–0234)—Extension

The Drug Addiction Treatment Act of 2000 (''DATA,'' Pub. L. 106–310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers. The legislation was amended in 2005 to eliminate the patient limit for physicians in group practices, and in 2006, to permit certain physicians to treat up to 100 patients.

To implement these provisions, SAMHSA developed a notification form (SMA–167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (*i.e.,* independent physicians) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner's registration under 21 U.S.C. 823(f).

Practitioners may use the form for three types of notification: (a) New, (b) immediate, and (c) to notify of their intent to treat up to 100 patients. Under ''new'' notifications, practitioners may make their initial waiver requests to SAMHSA. ''Immediate'' notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). Finally, the form may be used by physicians with waivers to certify their need and intent to treat up to 100 patients.

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; email address; name and address of group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification new, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information to the *SAMHSA Buprenorphine Physician Locator.*

Since July 2002, SAMHSA has received over 25,000 notifications and has certified almost 27,000 physicians. Fifty-one percent of the notifications were submitted by mail or by facsimile, with approximately forty-one percent submitted through the Web based online system. Approximately 60 percent of the certified physicians have consented to disclosure on the *SAMHSA Buprenorphine Physician Locator.*

Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

There are no changes to the forms and burden hours.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of submission	Number of respondents	Responses per respondent	Burden per response (hr.)	Total Burden (hrs.)
Initial Application for Waiver	1,500	1	.083	125
Notification to Prescribe Immediately	50	1	.083	4
Notice to Treat up to 100 patients	500	1	.040	20
Total	2,050			149

Written comments and recommendations concerning the proposed information collection should be sent by May 14, 2012, to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2012–8797 Filed 4–11–12; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form (OMB No. 0930–0295)—Revision

This request is for a three-year generic clearance to continue rapid HIV testing data collection among 63 TCE–HIV Grantees and their clients and the additional 11 MAI–HIV Grantees and their clients. The primary purpose of the MAI Rapid HIV Testing Clinical Information Form is to use a standardized data collection instrument to fully capture essential clinical information to enhance preventive services for those who test HIV-negative and refer to quality treatment/medical care those who test HIV-positive.

The aim of the project is to implement and increase rapid HIV testing among racial and ethnic minorities and collect rapid HIV testing data using the MAI Rapid HIV Testing Clinical Information Form. To meet this requirement, all Grantees must offer their clients rapid HIV preliminary antibody testing during outreach, pretreatment, or program enrollment. In addition, rapid HIV testing may be made available to the sexual and/or injection partners of clients. Grantees must provide onsite rapid HIV testing in accordance with their respective State and local requirements. If a client requests an off-site rapid HIV test, the Grantee must provide a referral to a rapid HIV testing site certified by the local health department.

Grantees are currently using the MAI Rapid HIV Testing Clinical Information Form in the field to systematically collect information from clients on demographics, previous rapid HIV test results, substance use and sexual risk behaviors, current rapid HIV test results, types of services received, and confirmatory HIV test result. Once a client is offered a rapid HIV test, the Grantee staff completes the MAI Rapid HIV Testing Clinical Information Form with the client present and then enters the data into a secure Web site that allows for real-time data submission.

The estimated annualized burden is summarized below.

Respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total burden hours
MAI Rapid HIV Testing Clinical Information Form (FY 2008 and FY 2009—63 Grantees)	10,000	1	0.133	1,330
RHT form for 11 HIV program FY 2011 grantees (public health departments)	20,000	1	0.133	2,660
MAI Rapid HIV Testing Clinical Information Form (Re-test)	6,000	1	0.133	798
Total	30,000			4,788

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8–1099, One Choke Cherry Road, Rockville, MD 20857 or email a copy to *summer.king@samhsa.hhs.gov*. Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

Summer King,

Statistician.

[FR Doc. 2012–8798 Filed 4–11–12; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 2013 National Survey on Drug Use and Health—(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

Data from clinical interviews completed in 2008 were combined with the main interview short scale data to develop a predictive model that was applied to the full main sample to estimate SMI. Follow-up clinical interviews continued to be conducted with NSDUH respondents from 2009 to 2012. Data from these interviews were analyzed annually to update the calibration of the screening measure. To maximize trend validity, this model has been applied to 2009–2011 data. With the completion of 1500 clinical interviews in 2012, SAMHSA will have accumulated a large enough sample (4,500) to update and improve the models. Therefore, the MHSS clinical interviewing will be discontinued in 2013.

For the 2013 NSDUH, a few questionnaire changes are proposed. The instrument has been updated to include new questions on military service, medical marijuana, physician substance use screening, and respondent characteristics.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2013 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

ESTIMATED BURDEN FOR 2013 NSDUH

Instrument	Number of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage rate	Annualized costs
Household Screening	145,474	1	0.083	12,074	$14.45	$174,469
Interview	67,500	1	1.000	67,500	14.45	975,375
Screening Verification	5,400	1	0.067	362	14.45	5,231
Interview Verification	10,125	1	0.067	678	14.45	9,797
Total	145,474	....	....	80,614	....	1,164,872

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8–1099, One Choke Cherry Road, Rockville, MD 20857 or email a copy at *summer.king@samhsa.hhs.gov*.

Written comments must be received before 60 days after the date of the publication in the **Federal Register**.

Summer King,

Statistician.

[FR Doc. 2012–8799 Filed 4–11–12; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase VI (OMB No. 0930–0307)—REVISION

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center of Mental Health Services is responsible for the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program (Children's Mental Health Initiative—CMHI) that will collect data on child mental health outcomes, family life, and service system development. Data will be collected on 47 service systems, and approximately 6,561 children and families.

Principal changes from the previous Phase VI OMB approval include:

• Addition of nine (9) communities awarded cooperative agreements in FY2010 for data collection.

• Replacement of intake and follow-up questionnaires for the Child Welfare Sector and Comparison Study with an administrative record review form to lessen burden.

• Addition of a brief 8-item Education Sector Caregiver Questionnaire to the Education Sector and Comparison Study to capture family involvement in the development and use of Individualized Education Plans (IEPs).

• Removal of data collection activities for the Alumni Networking Study, the CQI Initiative Evaluation, and the Sustainability Study.

Data collection for this evaluation will be conducted over a five-year period. Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The length of time that individual families will participate in the study is up to 24 months. The outcome measures include the following: child symptomatology and functioning, family functioning, satisfaction, and caregiver strain. The core of service system data will be collected every 18–24 months throughout the 5-year evaluation period. Service utilization and cost data will be tracked and submitted to the national evaluation every six months using two tools: the Flex Fund Tool and the Services and Costs Data Tool to estimate average cost of treatment per child, distribution of costs, and allocation of costs across service categories. Service delivery and system variables of interest include the following: maturity of system of care development in funded system of care communities, adherence to the system of care program model, and client service experience.

In addition, the evaluation will include one special study: The Sector and Comparison Study will examine in more detail the outcomes and service experience of children from multiple child-serving sectors and, through child-level matching, compare these outcomes with those not receiving system of care services.

Internet-based technology such as data entry and management tools will be used in this evaluation. The measures of the national evaluation address annual Congressional reporting requirements of the program's authorizing legislation, and the national outcome measures for mental health programs as currently established by SAMHSA.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take to complete each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-Year average annual burden hours
System of Care Assessment						
Interview Guides A–S	Key site informants	1,081	3	1.00	3,243	649
Child and Family Outcome Study						
Caregiver Information Questionnaire, Revised: Caregiver—Intake (CIQ–RC–I). Caregiver Information Questionnaire, Revised: Staff as Caregiver—Intake (CIQ–RS–I).	Caregiver Staff as Caregiver.	6,561	1	0.37	2,406	481

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-Year average annual burden hours
Caregiver Information Questionnaire, Revised: Caregiver—Follow-Up (CIQ–RC–F).	Caregiver	6,561	4	0.28	7,436	1,487
Caregiver Information Questionnaire, Revised: Staff as Caregiver—Follow-Up (CIQ–RS–F).	Staff as Caregiver.					
Caregiver Strain Questionnaire (CGSQ).	Caregiver	6,561	5	0.17	5,478	1,096
Child Behavior Checklist 1½–5 (CBCL 1½–5).	Caregiver	6,561	5	0.33	10,924	2,185
Child Behavior Checklist 6–18 (CBCL 6–18)						
Education Questionnaire, Revision 2 (EQ–R2).	Caregiver	6,561	5	0.33	10,924	2,185
Living Situations Questionnaire (LSQ).	Caregiver	6,561	5	0.08	2,723	545
Behavioral and Emotional Rating Scale—Second Edition, Parent Rating Scale (BERS–2C).	Caregiver	5,389	5	0.17	4,500	900
Columbia Impairment Scale (CIS).	Caregiver	6,281	5	0.08	2,607	521
Parenting Stress Index (PSI).	Caregiver	2,151	5	0.08	896	179
Devereux Early Childhood Assessment for Infants (DECA 1–18M).	Caregiver	1,576	5	0.08	657	131
Devereux Early Childhood Assessment for Toddlers (DECA 18–36M)						
Devereux Early Childhood Assessment (DECA 2–5Y)						
Preschool Behavioral and Emotional Rating (PreBERS).	Caregiver	1,576	5	0.10	788	158
Delinquency Survey, Revised (DS–R).	Youth	3,986	5	0.13	2,657	531
Behavioral and Emotional Rating Scale—Second Edition, Youth Rating Scale (BERS–2Y).	Youth	3,986	5	0.17	3,328	666
Gain Quick–R: Substance Problem Scale (GAIN).	Youth	3,986	5	0.08	1,654	331
Substance Use Survey, Revised (SUS–R).	Youth	3,986	5	0.10	1,993	399
Revised Children's Manifest Anxiety Scale, Second Edition (RCMAS–2).	Youth	3,986	5	0.07	1,329	266
Reynolds Adolescent Depression Scale, Second Edition (RADS–2).	Youth	3,986	5	0.05	997	199
Youth Information Questionnaire, Revised—Intake (YIQ–R–I).	Youth	3,986	1	0.25	997	199
Youth Information Questionnaire, Revised—Follow-Up (YIQ–R–F).	Youth	3,986	4	0.25	3,986	797
Service Experience Study						
Multi-Sector Service Contacts, Revised: Caregiver—Intake (MSSC–RC–I).	Caregiver	6,561	1	0.25	1,640	328

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-Year average annual burden hours
Multi-Sector Service Contacts, Revised: Staff as Caregiver—Intake (MSSC–RS–I).	Staff as Caregiver.					
Multi-Sector Service Contacts, Revised: Caregiver—Follow-Up (MSSC–RC–F).	Caregiver	6,561	4	0.25	6,561	1,312
Multi-Sector Service Contacts, Revised: Staff as Caregiver—Follow-Up (MSSC–RS–F).	Staff as Caregiver.					
Cultural Competence and Service Provision Questionnaire, Revised (CCSP–R).	Caregiver	6,561	4	0.13	3,499	700
Youth Services Survey for Families (YSS–F).	Caregiver	6,561	4	0.12	3,071	614
Youth Services Survey (YSS).	Youth	3,986	4	0.08	1,323	265
Comparison and Sector Study: Juvenile Justice						
Court Representative Questionnaire (CRQ).	Court representatives	202	5	0.50	505	101
Electronic Data Transfer of Juvenile Justice Records.	Key site personnel	202	5	0.03	34	7
Comparison and Sector Study: Education						
Teacher Questionnaire (TQ)	Teacher	202	5	0.50	505	101
School Administrator Questionnaire (SAQ).	School administrators	202	5	0.50	505	101
Electronic Data Transfer of Education Records.	Key site personnel	202	5	0.03	34	7
Education Sector Caregiver Questionnaire (ESCQ).	Caregiver	202	5	0.08	81	16
Comparison and Sector Study: Child Welfare						
Electronic Data Transfer of Child Welfare Records.	Key site personnel	202	5	0.03	34	7
Services and Costs Study						
Flex Funds Data Dictionary/Tool.	Local programming staff compiling/entering administrative data on children/youth.	1,565	3	0.03	155	31
Services and Costs Data Dictionary/Data Entry Application.	Local evaluator, staff at partner agencies, and programming staff compiling/entering service and cost records on children/youth.	6,561	100	0.05	32,805	6,561

Respondent	Number of respondents	Number of responses/respondent	Average burden/response	Total average annual burden
Caregiver	6,561	0.9	2.2	12,838
Youth	3,986	0.9	1.1	3,653
Provider/Administrator	1,081	12.9	0.5	7,564
Total	11,628			24,055

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8–1099, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at *summer.king@samhsa.hhs.gov.*

Written comments should be received within 60 days of this notice.

Summer King,

Statistician.

[FR Doc. 2012–8803 Filed 4–11–12; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2012–0001]

Critical Infrastructure Private Sector Clearance Program Request

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-day notice and request for comments; Reinstatement, with change, of a previously approved collection.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP) will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until June 11, 2012. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to DHS/NPPD/IP/Monika Junker, 245 Murray Lane, SW., Mail Stop 0609, Arlington, VA 20598–0609. Emailed requests should go to Monika Junker, *monika.junker@dhs.gov.* Written comments should reach the contact person listed no later than June 11, 2012. Comments must be identified by ''DHS–2012–0001''and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Email:* Include the docket number in the subject line of the message.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

SUPPLEMENTARY INFORMATION: The Critical Infrastructure Private Sector Clearance Program (PSCP) sponsors clearances for private sector partners who are responsible for critical infrastructure protection, but would not otherwise be eligible for a clearance under Executive Order 12829. These partners are subject matter experts within specific industries and sectors. The PSCP requires individuals to complete a clearance request form that initiates the clearance process. DHS Sector Specialists or Protective Security Advisors email the form to the individual who then emails back the completed form, minus their date and place of birth and social security number. The clearance request form is signed by both the Federal official who nominated the applicant and by the Assistant Secretary for Infrastructure Protection. Upon approval to process, the PSCP Administrator will contact the nominee to obtain the social security number, date and place of birth, and will then enter this data into e-QIP—Office of Personnel Management's secure portal for investigation processing. Once the data is entered in e-QIP, the applicant can complete the online security questionnaire. The PSCP maintains all applicants' information in the Master Roster, which contains all the information found on the clearance request form in addition to their clearance information (date granted, level of clearance, date non-disclosure agreements signed, and type/date of investigation). The Administrator of the Master Roster maintains the information so as to track clearance processing and investigation information and to have the most current contact information for the participants from each sector.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection.

Title: Critical Infrastructure Private Sector Clearance Program Request.

OMB Number: 1670–0013.

Frequency: Once.

Affected Public: Designated private sector employees of critical infrastructure entities or organizations.

Number of Respondents: 450 (estimate).

Estimated Time per Respondent: 10 minutes.

Total Burden Hours: 75.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost (operating/maintaining): $0.

Dated: April 4, 2012.

David Epperson,

Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2012–8738 Filed 4–11–12; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2012–0016]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding Information Collection Requests (ICRs), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625–0035, Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159). Additionally, the U.S. Coast Guard requests an extension of its approval for the following collection of information: 1625–0079, Standards of Training, Certification and Watchkeeping for Seafarers (STCW), 1995 and 1997 Amendments to the International Convention. Our ICRs describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before May 14, 2012.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2012–0016] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulations.gov.* (b) To OIRA by email via: *OIRA-submission@omb.eop.gov.*

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–611), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2100 2nd St. SW., Stop 7101, Washington DC 20593–7101.

FOR FURTHER INFORMATION CONTACT: Ms. Kenlinishia Tyler, Office of Information Management, telephone 202–475–3652 or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collections being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collections; (2) the accuracy of the estimated burden of the Collections; (3) ways to enhance the quality, utility, and clarity of information subject to the Collections; and (4) ways to minimize the burden of the Collections on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICRs referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2012–0016], and must be received by May 14, 2012. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2012–0016], indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov,* and type ''USCG–2012–0016'' in the ''Keyword'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0016'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625–0035 and 1625–0079.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (77 FR 5816, February 6, 2012) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Requests

1. *Title:* Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159).

OMB Control Number: 1625–0035.

Type of Request: Revision of a currently approved collection.

Respondents: Manufacturers of safety equipment, materials and marine sanitation devices.

Abstract: This information is used by the Coast Guard to ensure that regulations governing specific types of safety equipment, material and Marine Sanitation Devices (MSDs) installed on commercial vessels and pleasure craft are met. Manufacturers are required to submit drawings, specifications, and laboratory test reports to the Coast Guard before any approval is given.

Forms: CGHQ–10030.

Burden Estimate: The estimated burden has decreased from 103,289 hours to 58,414 hours a year.

2. *Title:* Standards of Training, Certification and Watchkeeping for Seafarers (STCW), 1995 and 1997 Amendments to the International Convention.

OMB control number: 1625–0079.

Type of Request: Extension of currently approved collection for the existing STCW requirements. **Note**—The Coast Guard has an ongoing rulemaking related to STCW [USCG–2004–17914; RIN 1625–AA16]. Comments related to that rulemaking are outside the scope of this extension request.

Respondents: Owners and operators of vessels, training institutions, and mariners.

Abstract: This information is necessary to ensure compliance with the international requirements of the STCW Convention, and to maintain an acceptable level of quality in activities associated with training and assessment of merchant mariners.

Forms: None.

Burden Estimate: The estimated burden remains 17,927 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: March 29, 2012.

R.E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2012–8826 Filed 4–11–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5444–N–02]

Federal Housing Administration (FHA): Multifamily Accelerated Processing (MAP)—Lender and Underwriter Eligibility Criteria and Credit Watch for MAP Lenders

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This proposed notice provides additional, detailed information to FHA-approved lenders and members of the public about HUD's processes for determining lender and underwriter eligibility and tier qualification for MAP participation. This proposed notice accompanies HUD's proposed rule on the same topic, published elsewhere in today's **Federal Register**. This notice includes the quantity, specific characteristics, and recentness of transactions that a lender or underwriter must have undertaken in order to qualify for each tier of MAP approval.

DATES: *Comment Due Date:* June 11, 2012.

ADDRESSES: Interested persons are invited to submit comments on this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service, toll-free, at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Terry W. Clark, Office of Multifamily Development, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6134, Washington DC 20410; telephone number (202) 402–2663 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Under its proposed rule, published elsewhere in today's **Federal Register**, HUD would revise 24 CFR part 200, subpart Y, to provide for tiered approval of new and existing MAP lenders and underwriters, such that only lenders and underwriters with adequate experience and qualifications could underwrite loans involving more complex multifamily housing programs and transactions.

II. Purpose

This proposed notice provides the tiered MAP approval lender and underwriter experience requirements referenced in the proposed amendment to 24 CFR part 200, ''Multifamily Accelerated Processing (MAP); MAP Lender Quality Assurance Enforcement.'' Under the terms of the proposed rule, HUD may establish and from time to time propose to revise these experience requirements for new and existing MAP lenders and underwriters, as market conditions or HUD's experience indicate would be prudent to adequately protect the FHA General Insurance Fund from unacceptable risk, through notice and the opportunity for public comment. The purpose of this notice is to propose the minimum number and type of closings required for MAP lender and underwriter approval at each qualification tier, and the time frame within which the loans must have closed within the tier to be found by HUD to be acceptable experience.

This practice would mitigate risk, since MAP lenders and underwriters will now be approved at a tier level commensurate to their demonstrated experience.

III. Tier Approval Experience Requirements

As would be provided in § 200.1411(b) of the proposed rule, an FHA lender or underwriter may use MAP to process or underwrite only those loan transactions that are covered by the lender or underwriter's MAP approval tier. The tiers are as follows:

Tier 1: Acquisition and refinancing programs (i.e., the FHA 223(f) or 223(a)(7) programs) without government subsidies;

Tier 2: Acquisition and refinancing programs (i.e., the FHA 223(f) or 223(a)(7) programs) with or without government subsidies;

Tier 3: All MAP-eligible programs (i.e., the FHA 220, 223(f), 223(a)(7), 221(d), 231, and 241 programs) without government subsidies; and

Tier 4: All MAP-eligible programs (i.e., the FHA 220, 223(f), 223(a)(7), 221(d), 231, and 241 programs), with or without government subsidies.

In accordance with § 200.1413(b) and § 200.1415(b) of the proposed rule, a MAP lender or underwriter would be approved at a tier level commensurate with the lender or underwriter's experience in underwriting and in processing transactions that are covered by that tier, or in underwriting and processing equivalent non-FHA loan transactions. (A non-FHA transaction may be deemed equivalent to a given FHA-covered loan transaction as provided in § 200.1413(b)(1)(i) or § 200.1415(a)(1), as applicable.) To qualify a lender or underwriter for MAP approval at a tier level, the loan transactions would be required to have closed and to be of the quantities, characteristics, and recentness provided in the following table:

Tier	Experience requirements
Tier 1	Five firm commitments issued or closings of 223(f) or closing of equivalent transactions within the past 5 years.
Tier 2	Five firm commitments issued or closings of 223(f) or closing of equivalent transactions within the past 5 years, and at least three of the transactions must have been with government subsidies.*
Tier 3	Five firm commitments issued or closings of 220, 221(d), 231, 232, or 241 or equivalent transactions within the past 5 years.
Tier 4	Five firm commitments issued or closings of 220, 221(d), 231, 232, or 241 or equivalent transactions within the past 5 years, and at least three of the transactions must have been with government subsidies.*

* See section II.A of the proposed rule's preamble for a discussion of qualifying government subsidies.

The requirement for new and existing lenders and underwriters to have undertaken five transactions within 5 years in order to demonstrate qualification at a tier represents an increase compared to HUD's current policy of requiring underwriters to have undertaken three transactions within 3 years for general MAP approval. HUD has observed that lenders whose underwriters had only three qualifying transactions within 3 years have often had insufficient familiarity with the programs and their responsibilities under the MAP program. To ensure appropriate management of risk to the FHA insurance fund, it is essential that new and existing MAP lenders and underwriters have adequate transactional experience before they undertake their first transaction pursuant to their MAP approval at a given tier. HUD, therefore, proposes to increase the minimum number of transactions to five, but, accordingly, to provide that the transactions must have occurred within 5 years of when approval is sought, rather than within 3 years.

Dated: March 16, 2012.

Carol J. Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–8679 Filed 4–11–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Proposed Renewal of Information Collection: Applicant Background Survey

AGENCY: U.S. Department of the Interior.

ACTION: Notice and Request for Comments.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Civil Rights, Office of the Secretary, Department of the Interior (DOI) announces the proposed extension of a public information collection and seeks public comments on the provisions thereof.

DATES: Consideration will be given to all comments received by June 11, 2012.

ADDRESSES: Send your written comments to the U.S. Department of the Interior, Office of the Secretary, Office of Civil Rights, Attn: Ophelia Anderson, Chief, Compliance and Programs Division, 1849 C St. NW., MS 4309 Main Interior Building, Washington, DC 20240. Send any faxed comments to (202) 208–6112, Attn: Ophelia Anderson. Comments may also be emailed to *Ophelia_Anderson@ios.doi.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this renewed information collection or its Applicant Background Survey Form should be directed to the above address. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

SUPPLEMENTARY INFORMATION:

I. Abstract

DOI is below parity with the Relevant Civilian Labor Force representation for many mission critical occupations. The DOI Strategic Plan identifies the job skills that will be needed in its current and future workforce. The job skills it will need are dispersed throughout its nine bureaus and include, among others, making visitors welcome to various facilities, such as parks and refuges, processing permits for a wide variety of uses of the public lands, collecting royalties for minerals extracted from the public lands, rounding-up and adopting-out wild horses and burros found in the west, protecting archeological and cultural resources of the public lands, and enforcing criminal laws of the United States. As a result of this broad spectrum of duties and services, the DOI touches the lives of most Americans.

The people who deal with the DOI bring with them a wide variety of backgrounds, cultures, and experiences. A diverse workforce enables the DOI to provide a measure of understanding to its customers by relating to the diverse background of those customers. By including employees of all backgrounds, all DOI employees gain a measure of knowledge, background, experience, and comfort in serving all of the DOI's customers.

In order to determine if there are barriers in our recruitment and selection processes, DOI must track the demographic groups that apply for its jobs. The most effective and statistically valid method to make these determinations is information directly from applicants. The data collected is not provided to selecting officials and plays no part in the merit staffing or the selection processes. The data collected will be used in summary form to determine trends covering the demographic make-up of applicant pools and job selections within a given occupation or organizational group. The records of those applicants not selected are destroyed in accordance with DOI's records management procedures.

II. Data

(1) Title: Applicant Background Survey.

OMB Control Number: 1091–0001.

Current Expiration Date: July 31, 2012.

Type of Review: Information Collection Renewal.

Affected Entities: Applicants for DOI jobs.

Estimated annual number of respondents: 13,433.

Frequency of Response: One per job application.

(2) Annual reporting and record keeping burden: Average reporting burden per application: 5 minutes.

Total annual reporting: 1,119 hours.

(3) Description of the need and use of the information: This information is required to obtain the source of recruitment, ethnicity, race, and disability data on job applicants to determine if the recruitment is effectively reaching all aspects of relevant labor pools and to determine if there are proportionate acceptance rates at various stages of the recruitment process. Response is optional. The information is used for evaluating recruitment only, and plays no part in the selection of who is hired.

III. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information.

All written comments will be available for public inspection in the Main Interior Building, 1849 C Street NW., Washington, DC during normal business hours, excluding legal holidays. For an appointment to inspect comments, please contact Ophelia Anderson by telephone on (202) 219–0805, or by email at *Ophelia_Anderson@ios.doi.gov.* A valid picture identification is required for entry into the Department of the interior.

Dated: April 5, 2012.

Sharon Eller,

Director, Office of Civil Rights, Office of the Secretary.

[FR Doc. 2012–8810 Filed 4–11–12; 8:45 am]

BILLING CODE 4310–RE–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2012–N027; FXES11130400000C2–123–FF04E00000]

Endangered and Threatened Wildlife and Plants; Notice of Availability of a Technical/Agency Draft Recovery Plan for Alabama Sturgeon

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and request for public comment.

SUMMARY: We, the Fish and Wildlife Service, announce the availability of the technical/agency draft recovery plan for the endangered Alabama Sturgeon. The draft recovery plan includes specific recovery objectives and criteria that would have to be met in order for us to downlist the species to be threatened under the Endangered Species Act of 1973, as amended (Act). We request review and comment on this draft recovery plan from local, State, and Federal agencies, and the public.

DATES: In order to be considered, comments on the draft recovery plan must be received on or before June 11, 2012.

ADDRESSES: If you wish to review this technical/agency draft recovery plan, you may obtain a copy by contacting Jeff Powell, U.S. Fish and Wildlife Service, Alabama Field Office, 1208–B Main Street, Daphne, AL 36532; tel. (251) 441–6630, or by visiting either the Service's recovery plan Web site at *http://endangered.fws.gov/recovery/index.html#plans* or the Daphne Field Office Web site at *http://www.fws.gov/daphne/.*

If you wish to comment, you may submit your comments by one of the following methods:

- You may submit written comments and materials to Jeff Powell, at the above address.
- You may hand-deliver written comments to our Alabama Field Office, at the above address, or fax them to (251) 441–6222.
- You may send comments by email to *jeff_powell@fws.gov.*

For additional information about submitting comments, see the ''Request for Public Comments'' section below.

FOR FURTHER INFORMATION CONTACT: Jeff Powell, at the above addresses or by telephone: (251) 441–5858.

SUPPLEMENTARY INFORMATION:

Background

The Alabama sturgeon (*Scaphirhyncus suttkusi*) was listed as an endangered species under the Act (16 U.S.C. 1531 *et seq.*) on May 5, 2000 (65 FR 26438). Its historic range encompassed all major rivers in the Mobile Basin, including the Alabama, Tombigbee, and Cahaba River systems, below the fall lines for each river. (Fall lines are changes in elevation (i.e., falls) that block navigation upstream by fish.) Recent collections of Alabama sturgeon have been restricted to the lower Alabama River, from below R.F. Henry Lock and Dam to the confluence of the Tombigbee River, and the lower Cahaba River near its confluence with the Alabama River; however, records are extremely rare. The last capture of an Alabama sturgeon was on April 3, 2007, by biologists at the Alabama Department of Conservation and Natural Resources (ADCNR). Critical habitat was designated for the species on June 2, 2009 (74 FR 26488). The Alabama sturgeon is one of the rarest fish in the nation and may be close to extinction.

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of our endangered species program. To help guide the recovery effort, we prepare recovery plans for most listed species. Recovery plans describe actions considered necessary for conservation of the species, establish criteria for downlisting or delisting, and estimate time and cost for implementing recovery measures.

The Act requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act requires us to provide a public notice and an opportunity for public review and comment during recovery plan development. We will consider all information we receive during a public comment period prior to approval of each new or revised recovery plan. We and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

Recovery Plan Components

The objective of this plan is to provide a framework for the recovery of the Alabama sturgeon, so that protection under the Act is no longer necessary. Delisting is not currently foreseeable, due to extreme curtailment of range and extensive modification to the riverine habitats. Therefore, if finalized, this draft recovery plan would establish downlisting criteria for the Alabama sturgeon so that it may be reclassified as threatened.

Downlisting of the Alabama sturgeon from endangered to threatened will be considered when: (1) A population consisting of approximately 500 sexually mature Alabama sturgeon is shown to be surviving and naturally reproducing in the Alabama/Cahaba Rivers; (2) population studies show that the Alabama sturgeon population is naturally recruiting (consisting of multiple age classes) and sustainable over a period of 20 years (2–3 generations), and no longer requires hatchery augmentation; and (3) an agreement is in place that ensures adequate flows are being delivered down the Alabama River to allow for successful development of sturgeon larvae, and that fish are able to move successfully both upstream and downstream at dams on the Alabama River.

Request for Public Comments

We request written comments on the draft recovery plan. We will consider all comments we receive by the date specified in **DATES** prior to final approval of the plan.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533 (f).

Dated: February 1, 2012.

Mark J. Musaus,

Acting Regional Director, Southeast Region.

[FR Doc. 2012–8744 Filed 4–11–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK930000 L16100000.DS0000.12XL]

Notice of Correction to Notice of Availability of the Draft Integrated Activity Plan/Environmental Impact Statement for the National Petroleum Reserve-Alaska and Announcement of Public Subsistence-Related Hearings

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of correction.

SUMMARY: On March 30, 2012, the Bureau of Land Management (BLM) published a Notice of Availability of the Draft Integrated Activity Plan (IAP)/Environmental Impact Statement (EIS) for the National Petroleum Reserve-Alaska and Announcement of Public Subsistence-Related Hearings in the **Federal Register** (77 FR 19318). The BLM inadvertently stated that the comments on the Draft IAP/EIS must be received by May 31, 2012. The BLM will accept public comments on the Draft IAP/EIS until June 1, 2012.

FOR FURTHER INFORMATION CONTACT: Jim Ducker, BLM Alaska State Office, 907–271–3130.

Ronald L. Dunton,

Acting State Director.

[FR Doc. 2012–8860 Filed 4–11–12; 8:45 am]

BILLING CODE 4310–JA–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–807]

Certain Digital Photo Frames and Image Display Devices and Components Thereof; Notice of Request for Written Submissions on Remedy, the Public Interest, and Bonding With Respect to Defaulting Respondent Aiptek International Inc.

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission is requesting briefing on remedy, the public interest, and bonding with respect to relief against respondent Aiptek International Inc. (''Aiptek'') of Hsinchu, Taiwan, which was previously found in default in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 27, 2011, based on a complaint filed by Technical Properties Limited, LLC (''TPL'') of Cupertino, California. 76 FR 59737–38. The complaint alleges a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital photo frames and image display devices and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 6,976,623; 7,162,549; 7,295,443; and 7,522,424. The complaint further alleges the existence of a domestic industry. The Commission's notice of investigation named twenty respondents including Aiptek. The Office of Unfair Import Investigations was not named as a party to this investigation. The complaint and notice of investigation were served on Aiptek on September 22, 2011. Aiptek failed to respond to the complaint and notice of investigation.

On November 18, 2011, the presiding administrative law judge (''ALJ'') issued an order to Aiptek to show cause why it should not be held in default. *See* ALJ's Order No. 13 (November 18, 2011). Aiptek failed to respond to the show cause order. The ALJ issued an initial determination (''ID'') on December 22, 2011, finding Aiptek in default, pursuant to 19 CFR 210.13 and 210.16, because respondent did not respond to the complaint, notice of investigation, and the ALJ's order to show cause. On January 9, 2012, the Commission issued notice of its determination not to review the ID finding Aiptek in default.

On March 8, 2012, complainant TPL filed a declaration requesting immediate relief against the defaulting respondent Aiptek pursuant to Commission rule 210.16(c)(1), 19 CFR 210.16(c)(1). Its declaration included proposed remedial orders for the Commission's consideration.

Section 337(g)(1) (19 U.S.C. 1337(g)(1)) and Commission Rule 210.16(c)(1) (19 CFR 210.16(c)(1)) authorize the Commission to order immediate limited relief against a respondent found in default, unless after consideration of the public interest factors, it finds that such relief should not issue. The Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry are either adversely affecting it or likely to do so. For background, *see In the Matter of Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

When the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* section 337(j), 19 U.S.C. 1337(j) and the Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainant is requested to state the dates that the patents at issue expire and the HTSUS numbers under which the accused products are imported. The written submissions must be filed no later than close of business on April 23, 2012. Reply submissions must be filed no later than the close of business on April 30, 2012. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must do so in accordance with Commission rule 210.4(f), 19 CFR 210.4(f) which requires electronic filing. The original document and 8 true copies thereof must also be filed on or before the deadlines stated above with the Office of the Secretary. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.16(c)(1) and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.16(c)(1) and 210.50).

Issued: April 9, 2012.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–8849 Filed 4–11–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–530]

Trade Facilitation in the East African Community: Recent Developments and Potential Benefits, Institution of Investigation and Request for Written Statements

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and request for written statements.

SUMMARY: Following receipt of a request on March 28, 2012, from the United States Trade Representative (USTR) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission

(Commission) instituted investigation No. 332–530, *Trade Facilitation in the East African Community: Recent Developments and Potential Benefits.*

DATES:

May 10, 2012: Deadline for filing written submissions.

July 2, 2012: Transmittal of Commission report to the USTR.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov/edis3-internal/app.*

FOR FURTHER INFORMATION CONTACT: Falan Yinug (202–205–2160 or *falan.yinug@usitc.gov*) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: As requested by the USTR, the Commission will conduct an investigation and prepare a report that summarizes recent developments relating to trade facilitation in the East African Community (EAC). The report will also describe the potential benefits of trade facilitation in the EAC countries, based on empirical studies and the experiences of other developing countries. As requested, the information in the report will be based principally on a review of the literature, and, to the extent the literature permits, include the following:

• A description of the present conditions and recent developments relating to the movement of goods to and from the countries of the EAC, including policies enforced at the border and procedures for their enforcement, as well as transport infrastructure. To the extent feasible, the report will address elements referenced in U.S. trade facilitation agreements, such as those between the United States and the Philippines, the United States and Uruguay, and trade facilitation chapters in U.S. free trade agreements. The description will focus on conditions in individual EAC countries as well as the EAC region as a whole.

• A summary of findings from the empirical literature on the benefits of overall trade facilitation improvements, such as effects on import and export volumes, export diversification, and economic development, including highlights of any notable findings specific to the EAC countries.

• Relevant sectoral case studies (particularly for industries where EAC countries have significant AGOA exports) from developing countries within and outside sub-Saharan Africa that illustrate the benefits of trade facilitation.

The USTR asked that the Commission provide its report no later than July 2, 2012.

Written Submissions: Because of the short time frame requested by the USTR, the Commission will not hold a public hearing in connection with this investigation. However, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received no later than 5:15 p.m., May 10, 2012. All written submissions must conform to the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12 noon eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Secretary (202–205–2595).

Any submissions that contain confidential business information (CBI) must also conform to the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

In his request letter the USTR said that he anticipates that the Commission's report will be made available to the public in its entirety, and asked that the Commission not include any confidential business information in the report it sends him. Accordingly, any confidential business information received by the Commission in this investigation and used in preparing this report will not be included in the report that the Commission sends to the USTR and will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.

Issued: April 9, 2012.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–8850 Filed 4–11–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–778]

Certain Equipment for Communications Networks, Including Switches, Routers, Gateways, Bridges, Wireless Access Points, Cable Modems, IP Phones and Products Containing Same; Determination Not To Review an Initial Determination; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 47) granting a joint motion to terminate the investigation in its entirety based on a settlement agreement. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 21, 2011, based on a complaint filed by MOSAID Technologies Inc. of Ottawa, Canada (''MOSAID''), alleging violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain equipment for communications networks, including switches, routers, gateways, bridges, wireless access points, cable modems, IP phones and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 7,035,280; 7,292,600; 7,830,858; 6,842,459; 7,633,966; and 5,841,360. 76 FR 36154–55 (June 21, 2011). The Notice of Investigation named the following as respondents: Cisco Systems, Inc. of San Jose, California; Cisco Consumer Products LLC of Irvine, California; Cisco Systems International B.V. of Amsterdam, Netherlands; and Scientific Atlanta LLC of Lawrenceville, California (collectively ''Respondents''). The Office of Unfair Import Investigations was named as a party.

On March 14, 2012, MOSAID and Respondents jointly filed to terminate the investigation in its entirety based on a settlement agreement, which was attached to the motion. On March 21, 2012, the parties supplemented their motion to identify additional agreements that concern the investigation.

On March 21, 2012, the ALJ issued the subject ID granting the joint motion to terminate the investigation in its entirety pursuant to section 210.21(b) of the Commission's Rules of Practice and Procedure (19 CFR 210. 21(b)). No petitions for review of the subject ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

By order of the Commission.

Issued: April 9, 2012.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–8851 Filed 4–11–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–NEW]

Agency Information Collection Activities: Proposed Collection; Comments Requested: September 11th Victim Compensation Fund Objection Form

ACTION: 30-Day Notice of Information Collection Under Review.

The Department of Justice (DOJ), Civil Division, September 11th Victim Compensation Fund, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register**, Volume 77, Number 20, Page 4827 on January 31, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 14, 2012. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the 8 digit OMB number for the collection or the title of the collection. If you have questions concerning the collection, please call Jonathan Olin, 202–514–5585.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Victim Compensation Objection Form.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: N/A. Civil Division.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Anyone expressing a potential objection to the filing of a claim by a purported personal representative of a deceased victim. Abstract: This form is to be submitted in connection with potential objections made to claims filed with the September 11th Victim Compensation Fund of 2001. The form asks that the objection be characterized and explained or be withdrawn.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 50 objectors with an average of 2.0 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 100 annual total burden hours associated with thiscollection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution

Square, 145 N Street NE., Room 2E–508, Washington, DC 20530.

Jerri Murray,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2012–8398 Filed 4–11–12; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances: Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on December 7, 2011, Meda Pharmaceuticals Inc., 705 Eldorado Street, Decatur, Illinois 62523, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for distribution to its customers.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than May 14, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance listed in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: April 2, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–8761 Filed 4–11–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Application, Lipomed, Inc.

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on January 30, 2012, Lipomed, Inc., One Broadway, Cambridge, Massachusetts 02142, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
4-methyl-N-methylcathinone (1248).	I
N–Ethylamphetamine (1475)	I
N,N–Dimethylamphetamine (1480).	I
Fenethylline (1503)	I
Aminorex (1585)	I
4–Methylaminorex (cis isomer) (1590).	I
Gamma Hydroxybutyric Acid (2010).	I
Methaqualone (2565)	I
Mecloqualone (2572)	I
1–Pentyl-3-(1-naphthoyl)indole (7118).	I
1–Butyl-3-(1-naphthoyl)-indole (7173).	I
1-[2-(4–Morpholinyl)ethyl]-3–1(1-naphthoyl) indole (7200).	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
5-(1,1–Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (7297)	I
5-(1,1–Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (7298)	I
Lysergic acid diethylamide (7315)	I
2,5–Dimethoxy-4-(n)-propylthiophenethylamine (7348).	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Parahexyl (7374)	I
Nabilone (7379)	I
Mescaline (7381)	I
3,4,5–Trimethoxyamphetamine (7390).	I
4–Bromo-2,5-dimethoxyamphetamine (7391).	I
4–Bromo-2,5-dimethoxyphenethylamine (7392).	I
4–Methyl-2,5-dimethoxyamphetamine (7395).	I
2,5–Dimethoxyamphetamine (7396).	I
2,5–Dimethoxy-4-ethylamphetamine (7399).	I
3,4–Methylenedioxyamphetamine (7400).	I
5–Methoxy-3,4-methylenedioxyamphetamine (7401).	I
N–Hydroxy-3,4-methylenedioxyamphetamine (7402).	I
3,4–Methylenedioxy-N-ethylamphetamine (7404).	I
3,4–Methylenedioxymethamphetamine (7405).	I
4–Methoxyamphetamine (7411)	I
5–Methoxy-N–N-dimethyltryptamine (7431).	I
Alpha-methyltryptamine (7432)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
5–Methoxy-N,N-diisopropyltryptamine (7439).	I
N–Ethyl-1-phenylcyclohexylamine (7455).	I
1-(1–Phenylcyclohexyl)pyrrolidine (7458).	I
1-[1-(2–Thienyl)cyclohexyl]piperidine (7470).	I
1-[1-(2–Thienyl)cyclohexyl]pyrrolidine (7473).	I
N–Ethyl-3-piperidyl benzilate (7482).	I
N–Methyl-3-piperidyl benzilate (7484).	I
N–Benzylpiperazine (7493)	I
3,4-methylenedioxypyrovalerone (7535).	I
3,4-methylenedioxy-N-methylcathinone (7540).	I
Alphaprodine (9010)	I
Acetyldihydrocodeine (9051)	I
Benzylmorphine (9052)	I
Codeine-N-oxide (9053)	I
Cyprenorphine (9054)	I
Desomorphine (9055)	I
Etorphine (except HCl) (9056)	I

Drug	Schedule
Etorphine HCl (9059)	I
Codeine methylbromide (9070)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Heroin (9200)	I
Hydromorphinol (9301)	I
Methyldesorphine (9302)	I
Methyldihydromorphine (9304)	I
Morphine methylbromide (9305)	I
Morphine methylsulfonate (9306)	I
Morphine-N-oxide (9307)	I
Myrophine (9308)	I
Nicocodeine (9309)	I
Nicomorphine (9312)	I
Normorphine (9313)	I
Pholcodine (9314)	I
Acetorphine (9319)	I
Acetylmethadol (9601)	I
Allylprodine (9602)	I
Alphacetylmethadol except levo-alphacetyl-methadol (9603).	I
Alphamethadol (9605)	I
Dioxaphetyl butyrate (9621)	I
Dipipanone (9622)	I
Ethylmethylthiambutene (9623)	I
Etonitazene (9624)	I
Etoxeridine (9625)	I
Furethidine (9626)	I
Hydroxypethidine (9627)	I
Ketobemidone (9628)	I
Levomoramide (9629)	I
Levophenacylmorphan (9631)	I
Morpheridine (9632)	I
Noracymethadol (9633)	I
Norlevorphanol (9634)	I
Normethadone (9635)	I
Norpipanone (9636)	I
Phenadoxone (9637)	I
Phenampromide (9638)	I
Phenoperidine (9641)	I
Piritramide (9642)	I
Proheptazine (9643)	I
Properidine (9644)	I
Racemoramide (9645)	I
Trimeperidine (9646)	I
Phenomorphan (9647)	I
Levo-alphacetylmethadol (9648)	I
Propiram (9649)	I
Tilidine (9750)	I
Para-Fluorofentanyl (9812)	I
3–Methylfentanyl (9813)	I
Acetyl-alpha-methylfentanyl (9815).	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Phenmetrazine (1631)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
1–Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
4–Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Alphaprodine (9010)	II
Anileridine (9020)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Meperidine intermediate-B (9233)	II
Metazocine (9240)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Metopon (9260)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Dihydroetorphine (9334)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Phenazocine (9715)	II
Piminodine (9730)	II
Racemethorphan (9732)	II
Racemorphan (9733)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Tapentadol (9780)	II
Bezitramide (9800)	II
Fentanyl (9801)	II

The company plans to import analytical reference standards for distribution to its customers for research and analytical purposes.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than May 14, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: April 2, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–8763 Filed 4–11–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice Of Registration; Cerilliant Corporation

By Notice dated January 6, 2012, and published in the **Federal Register** on January 17, 2012, 77 FR 2321, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Fenethylline (1503)	I
Gamma Hydroxybutyric Acid (2010).	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315) Drug Schedule.	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348).	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
3,4,5-Trimethoxyamphetamine (7390).	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
4-Bromo-2,5-dimethoxyphenethylamine (7392).	I
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
2,5-Dimethoxyamphetamine (7396).	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxymethamphetamine (7405).	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-N-N-dimethyltryptamine (7431).	I

Drug	Schedule
Alpha-methyltryptamine (7432)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
5-Methoxy-N,N-diisopropyltryptamine (7439).	I
N-Benzylpiperazine (7493)	I
Etorphine (except HCl) (9056)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Pholcodine (9314)	I
Dextromoramide (9613)	I
Dipipanone (9622)	I
Racemoramide (9645)	I
Drug Schedule.	
Trimeperidine (9646)	I
Tilidine (9750)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Meperidine (9230)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Poppy Straw Concentrate (9670)	II
Fentanyl (9801)	II

The company plans to import small quantities of the listed controlled substances for the manufacture of analytical reference standards.

In reference to drug codes 7360 and 7370, the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for this drug code is authorized for this registration.

Comments and requests for hearings on applications to import narcotic raw material are not appropriate, 72 FR 3417 (2007). Regarding all other basic classes of controlled substances, no comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Cerilliant Corporation to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Cerilliant Corporation to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: April 2, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–8766 Filed 4–11–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1586]

Hearing of the Attorney General's National Task Force on Children Exposed to Violence

AGENCY: Office of Justice Programs (OJP), Justice.

ACTION: Notice of hearing.

SUMMARY: This is an announcement of the fourth hearing of the Attorney General's National Task Force on Children Exposed to Violence (the ''task force''). The task force is chartered to provide OJP, a component of the Department of Justice, with valuable advice in the areas of children exposed to violence for the purpose of addressing the epidemic levels of exposure to violence faced by our nation's children. Based on the testimony at four public hearings; comprehensive research; and extensive input from experts, advocates, and impacted families and communities nationwide, the task force will issue a final report to the Attorney General presenting its findings and comprehensive policy recommendations in the fall of 2012.

DATES: The hearing will take place on Monday, April 23; Tuesday, April 24; and Wednesday, April 25, 2012.

ADDRESSES: The hearing will take place at Wayne State University in the Bernath Auditorium on the first floor of the David Adamany Undergraduate Library, 5155 Gullen Mall, Detroit, MI 48202.

FOR FURTHER INFORMATION CONTACT: Will Bronson, Designated Federal Official (DFO), Deputy Associate Administrator, Child Protection Division, Office of Juvenile Justice & Delinquency Prevention, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531. Phone: (202) 305–2427 [note: this is not a toll-free number]; email: *willie.bronson@usdoj.gov.*

SUPPLEMENTARY INFORMATION: This hearing is being convened to brief the task force members about the issue of children's exposure to violence. The final agenda is subject to adjustment, but it is anticipated that on April 23, there will be an evening session devoted to public testimony. On April 24, there will be a morning and afternoon session, with a break for lunch. The morning session will likely include welcoming remarks, introductions, and panel presentations from invited guests on the impact of children's exposure to violence. The afternoon session will continue with panel presentations from invited guests. April 25 will likely be devoted to a working meeting of task force members.

This meeting is open to the public. Members of the public who wish to attend this meeting must provide photo identification upon entering the hearing facility. Access to the meeting will not be allowed without identification. In order to best prepare for attendees, members of the public who wish to attend this meeting may register with Will Bronson at *defendingchildhood taskforce@nccdcrc.org* in advance of the meeting. Registrations will be accepted on a space available basis. Prior registration is not required to attend this event, but is required for those who wish to provide testimony.

Time for public testimony is scheduled from 5 p.m. to 7 p.m. Eastern on April 23. Public testimony must be provided in person and will be limited to three (3) minutes per witness. Members of the public who wish to provide testimony must register with Will Bronson at *defendingchildhoodtask force@nccdcrc.org* by April 20. Please bring photo identification and allow extra time prior to the meeting. Persons interested in communicating with the task force should submit their written comments to the DFO at *defendingchild hoodtaskforce@nccdcrc.org*, as the time available will not allow the public to directly address the task force (except as provided above) at the meeting.

Anyone requiring special accommodations should notify Mr.

Bronson at least seven (7) days in advance of the meeting.

Catherine Pierce,

Associate Administrator, Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention, Child Protection Division.

[FR Doc. 2012–8861 Filed 4–11–12; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Evaluation of the Unemployment Compensation Provisions of the American Recovery and Reinvestment Act of 2009

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting, under the Departmental Management (DM) Account, the information collection request (ICR) proposal titled, ''Evaluation of the Unemployment Compensation Provisions of the American Recovery and Reinvestment Act of 2009,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before May 14, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–DM, Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This information collection is in support of an evaluation of the unemployment compensation (UC) provisions of the American Recovery and Reinvestment Act (ARRA) of 2009. The evaluation is designed to provide insights into five topics: (1) States' decisions to adopt certain UC-related reforms encouraged by the ARRA, (2) states' implementation experiences with these ARRA UC provisions, (3) the characteristics of recipients of different types of unemployment benefits during the time ARRA-related UC benefits were available, (4) the impact of ARRA UC provisions on recipients' outcomes, and (5) additional research questions about the influence of the UC provisions of the ARRA on macroeconomic issues and state unemployment insurance (UI) trust funds. This package requests clearance for three data collection efforts conducted as part of the evaluation: (1) Survey of UI Recipients, (2) Survey of UI Administrators, and (3) Site Visit Data Collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL seeks OMB approval for this information collection under OMB ICR Reference Number 201110–1225–001. For additional information, see the related notice published in the **Federal Register** on December 12, 2011 (76 FR 77260).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should reference OMB ICR Reference Number 121110–1225–001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–DM.

Title of Collection: Evaluation of the Unemployment Compensation Provisions of the American Recovery and Reinvestment Act of 2009.

OMB ICR Reference Number: 201110–1225–001.

Affected Public: Individuals or Households; Private Sector—For Profit Entities; State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 2,491.

Total Estimated Number of Responses: 2,901.

Total Estimated Annual Burden Hours: 1,801.

Total Estimated Annual Other Costs Burden: $0.

Dated: April 4, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–8776 Filed 4–11–12; 8:45 am]

BILLING CODE 4510–22–P

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Collection of Follow-up Survey Information for Green Jobs and Health Care Impact Evaluation of American Recovery and Reinvestment Act (ARRA)-Funded Grants; New Collection

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department or DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork

Reduction Act of 1995 [44 U.S.C. 3505(c)(2)(A)]. The program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of the collection requirements on respondents can be properly assessed.

The proposed follow-up survey information collection is for an evaluation of the impact of the Green Jobs and Health Care ARRA-funded training grants. This evaluation is sponsored by ETA to understand the processes surrounding the design and implementation of these grants.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before June 11, 2012.

ADDRESSES: A copy of this proposed information collection request may be obtained by contacting Savi Swick at 202–693–3382 (this is not a toll-free number) or email: *swick.savi@dol.gov.* Comments are to be submitted to Department of Labor/Employment and Training Administration, Attn: Savi Swick, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210. Written comments may be transmitted by facsimile to 202–693–2766 (this is not a toll-free number) or emailed to *swick.savi@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The proposed follow-up survey information collection is for an evaluation of the impacts of the Green Jobs and Health Care (GJHC) training grants. This evaluation is sponsored by ETA for worker training and placement in high growth and emerging industries through training grants.

In February 2009, President Obama signed the ARRA into law in an effort to preserve and create jobs, promote economic growth, and assist those impacted by the recession. The ARRA included funding for four Solicitations for Grant Applications (SGAs) with the goal of training workers in the skills required to be employed in specific high-growth and emerging industries including health care, energy efficiency, and renewable energy. This study focuses on the following two SGAs:

- Pathways Out of Poverty (POP) ($150 million for 38 projects).
- Health Care and Other High Growth Emerging Industries (HHG) ($225 million for 55 projects).

The overall aim of this evaluation is to determine the extent to which enrollees achieve increases in employment, earnings, and career advancement because of their participation in the training provided by POP and HHG grantees and to identify promising best practices and strategies for replication. Individuals enrolling in the GJHC training programs have a 50/50 chance of receiving these services. Those individuals not receiving the training services receive the existing services offered by the grantee. Education, employment, and other outcomes of the two groups will be compared over time to evaluate the GJHC training grant impact. The evaluation will estimate the success in providing educational and occupational skills training that fosters entry into job fields that are innovative and/or experiencing high growth, as in the health care industry.

II. Review Focus

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

III. Current Actions

This proposed information collection will involve collecting data from recipients of four DOL/ETA grants that provide funding to train unemployed, underemployed, dislocated, and incumbent workers for employment and to create career pathways in health care and other growing industries.

Agency: Employment and Training Administration.

Type of Review: New Collection.

Title of Collection: Follow-up Survey Information for Green Jobs and Health Care Impact Evaluation of ARRA-funded Grants.

OMB Control Number: 1205–0NEW.

Affected Public: Individuals or households; State, local, and Tribal Governments.

Estimated Number of Respondents: 4,024.

Frequency: Once at 18 months and once at 36 months.

Total Estimated Annual Responses: 4,024.

Estimated Total Annual Burden Hours: 4,426.

Total Annualized Capital and Startup Costs: $0.

Total Annualized Operation and Maintenance Costs: $0.

Total Estimated Annual Cost Burden: $85,953.

Data collection activity	Number of respondents	Total burden hours	Average hourly wage rate	Total annualized cost
Follow-up Surveys:				
a. 18-month	4,024	2,213	$19.42	$42,976.5
b. 36-month	4,024	2,213	19.42	42,976.5
TOTAL	4,024	4,426	n/a	85,953

Comments submitted in response to this notice will be summarized and may be included in the request for Office of Management and Budget approval of the final information collection request. The comments will become a matter of public record.

Dated: Signed at Washington, DC on this 3rd day of April, 2012.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2012–8724 Filed 4–11–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act; Native American Employment and Training Council

AGENCY: Employment and Training Administration, U.S. Department of Labor.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Section 10 (a)(2) of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, and Section 166 (h)(4) of the Workforce Investment Act (WIA) [29 U.S.C. 2911(h)(4)], notice is hereby given of the next meeting of the Native American Employment and Training Council (Council), as constituted under WIA.

DATES: The meeting will begin at 1:30 p.m. (Eastern Time) on Thursday, April 26, 2012, and continue until 5 p.m. that day. The meeting will reconvene at 9 a.m. on Friday, April 27, 2012, and adjourn at 3 p.m. that day. The period from 2:30 p.m. to 4:30 p.m. on April 26, 2012, will be reserved for participation and presentations by members of the public.

ADDRESSES: The meeting will be held at the Tunica-Biloxi Tribal Museum and Cultural Resources Center, 151 Melacon Drive, Marksville, Louisiana 71351.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Members of the public not present may submit a written statement on or before April 18, 2012, to be included in the record of the meeting. Statements are to be submitted to Mrs. Evangeline M. Campbell, Designated Federal Official (DFO), U.S. Department of Labor, 200 Constitution Avenue NW., Room S–4209, Washington, DC 20210. Persons who need special accommodations should contact Mr. Craig Lewis at (202) 693–3384, at least two business days before the meeting. The formal agenda will focus on the following topics: (1) U.S. Department of Labor (DOL), Employment and Training Administration Update; (2) U.S. Department of Labor, Office of Public Engagement—Tribal Consultation Policy (TCP) Update; (3) DOL, Division of Indian and Native American Program Update; (4) Training and Technical Assistance; (5) Council Update; (6) Council Workgroup Reports; and (7) Council Recommendations.

FOR FURTHER INFORMATION CONTACT: Mrs. Evangeline M. Campbell, DFO, Division of Indian and Native American Programs, Employment and Training Administration, U.S. Department of Labor, Room S–4209, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number (202) 693–3737 (VOICE) (this is not a toll-free number).

Signed at Washington, DC, this 4th day of April, 2012.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2012–8725 Filed 4–11–12; 8:45 am]

BILLING CODE 4501–FR–P

OFFICE OF MANAGEMENT AND BUDGET

Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of availability and request for comments.

SUMMARY: The Office of Management and Budget (OMB) requests comments on its Draft 2012 Report to Congress on the Benefits and Costs of Federal Regulations, available at: *http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/.* The Draft Report is divided into four chapters. Chapter I examines the benefits and costs of major Federal regulations issued in Fiscal Year 2011 and summarizes the benefits and costs of major regulations issued between October 2001 and September 2011. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II offers recommendations for regulatory reform. Chapter III provides an update on implementation of the Information Quality Act. Chapter IV summarizes agency compliance with the Unfunded Mandates Reform Act. OMB requests that comments be submitted electronically to OMB within 60 days from the date of notice publication in the **Federal Register** through *www.regulations.gov.*

DATES: To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by 60 days after publication.

ADDRESSES: Submit comments by one of the following methods:

- *www.regulations.gov:* Direct comments to Docket ID OMB–2010–0008
- *Fax:* (202) 395–7285.
- *Mail:* Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mabel Echols, NEOB, Room 10202, 725 17th Street NW., Washington, DC 20503. To ensure that your comments are received, we recommend that comments on this draft report be electronically submitted.

All comments and recommendations submitted in response to this notice will be made available to the public, including by posting them on OMB's Web site. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means OMB will not know your identity or contact information unless you provide it in the body of your comment.

For Further Information, contact: Mabel Echols, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10202, 725 17th Street NW., Washington, DC 20503. Telephone: (202) 395–3741.

SUPPLEMENTARY INFORMATION: Congress directed the Office of Management and Budget (OMB) to prepare an annual Report to Congress on the Costs and Benefits of Federal Regulations. Specifically, Section 624 of the FY 2001 Treasury and General Government Appropriations Act, also known as the ''Regulatory Right-to-Know Act,'' (the Act) requires OMB to submit a report on the costs and benefits of Federal regulations together with recommendation for reform. The Act states that the report should contain estimates of the costs and benefits of regulations in the aggregate, by agency and agency program, and by major rule, as well as an analysis of impacts of Federal regulation on State, local, and tribal governments, small businesses, wages, and economic growth. The Act also states that the report should be subject to notice and comment and peer review.

Cass R. Sunstein,

Administrator, Office of Information and Regulatory Affairs.

[FR Doc. 2012–8533 Filed 4–11–12; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by May 14, 2012. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Polly A. Penhale at the above address or (703) 292–7420.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

1. *Applicant:*

Permit Application: 2013–001

William R. Fraser, Polar Oceans Research Group, P.O. Box 366, Sheridan, MT 59749.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Areas (ASPA's), Take, and Import into the USA. The applicant conducts research as part of the Palmer Station Long-Term Ecological Research Program. The applicant plans to enter the Antarctic Specially Protected areas of ASPA 107–Dion Islands, ASPA 113–Litchfield Island, ASPA 115–Lagotellerie Island, ASPA–117–Avian Island, and ASPA 139–Biscoe Point to conduct his research. He plans to take by capture and release to (1) census populations and mark breeding territories; (2) capture, mark, band and/or weigh adult, chicks and eggs of seabirds (Adelie, Chinstrap, and Gentoo penguins, Brown Skua, South Polar Skua, S. Giant Petrel, Blue-Eyed Shag, and Kelp Gulls), (3) obtain diet samples by stomach lavage, by screening contents of terrestrial sediment traps and/or by collecting regurgitated prey items; (4) place transmitters on individuals; (5) place instrumented artificial eggs under incubating individuals; (6) obtain tissue samples from adults and chicks (e.g. preen gland oil, blood, feathers, yolk); (7) collect addled/infertile eggs no longer being incubated; (8) use GPS/GIS technologies to update existing breeding habitat maps, and (9) salvage dead specimens in good condition for educational purposes.

Location

Palmer Station area, Marguerite Bay including ASPA 107–Dion Islands, ASPA 113–Litchfield Island, ASPA 115–Lagotellerie Island, ASPA–117–Avian Island, and ASPA 139–Biscoe Point.

Dates

October 1, 2012 to 30 September 30, 2017.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. 2012–8726 Filed 4–11–12; 8:45 am]

BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213

Extension:

Form TH, OMB Control No. 3235–0425, SEC File No. 270–377.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form TH (17 CFR 239.65, 249.447, 269.10 and 274.404) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*), the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), the Trust Indenture Act of 1939 (15 U.S.C. 77aaa *et seq.*) and the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) is used by registrants to notify the Commission that an electronic filer is relying on the temporary hardship exemption for the filing of a document in paper form that would otherwise be required to be filed electronically as prescribed by Rule 201(a) of Regulation S–T. Form TH must be filed every time an electronic filer experiences unanticipated technical difficulties preventing the timely preparation and submission of a required electronic filing. Approximately 70 registrants file Form TH and it takes an estimated 0.33 hours per response for a total annual burden of 23 hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: April 6, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8796 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Regulation FD, OMB Control No. 3235–0536, SEC File No. 270–475.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Regulation FD (17 CFR 243.100 *et seq.*)—Other Disclosure Materials requires public disclosure of material information from issuers of publicly traded securities so that investors have current information upon which to base investment decisions. The purpose of the regulation is to require: (1) An issuer that intentionally discloses material information, to do so through public disclosure, not selective disclosure; and (2) to make prompt public disclosure of material information that was unintentionally selectively disclosed. We estimate that approximately 13,000 issuers make Regulation FD disclosures approximately five times a year for a total of 58,000 submissions annually, not including an estimated 7,000 issuers who file Form 8–K to comply with Regulation FD. We estimate that it takes 5 hours per response (58,000 responses × 5 hours) for a total burden of 290,000 hours annually. In addition, we estimate that 25% of the 5 hours per response (1.25 hours) is prepared by the filer for an annual reporting burden of 72,500 hours (1.25 hours per response × 58,000 responses).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: April 6, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8795 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Form F–9, OMB Control No. 3235–0377, SEC File No. 270–333.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management Budget for extension and approval.

Form F–9 (17 CFR 239.39) is a registration statement under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) that is used to register investment grade debt or investment grade preferred securities that are offered for cash or in connection with an exchange offer and are either non-convertible or not convertible for a period of at least one year from the date of issuance and thereafter are only convertible into a security of another class of the issuer. The purpose of the information collection is to permit verification of compliance with securities law requirements and to assure the public availability and dissemination of such information. The principal function of the Commission's forms and rules under the securities laws' disclosure provisions is to make information available to the investors. We estimate that Form F–9 takes approximately 25 hours per response and it is filed by 18 respondents. We further estimate that 25% of the 25 hours per response (6.25 hours) is prepared by the issuer for an annual reporting burden of 113 hours (6.25 hours per response × 18 responses).

Written comments are invited on: (a) Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: April 6, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8794 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Extension of Existing Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Interagency Statement on Sound Practices, OMB Control No. 3235–0622, SEC File No. 270–560.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in the proposed Interagency Statement on Sound

Practices Concerning Elevated Risk Complex Structured Finance Activities (''Statement'') under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'') and the Investment Advisers Act of 1940 (15 U.S.C. 80b *et seq.*) (''Advisers Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The Statement was issued by the Commission, together with the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision (together, the ''Agencies''), in May 2006. The Statement describes the types of internal controls and risk management procedures that the Agencies believe are particularly effective in assisting financial institutions to identify and address the reputational, legal, and other risks associated with elevated risk complex structured finance transactions.

The primary purpose of the Statement is to ensure that these transactions receive enhanced scrutiny by the institution and to ensure that the institution does not participate in illegal or inappropriate transactions.

The Commission estimates that approximately 5 registered broker-dealers or investment advisers will spend an average of approximately 25 hours per year complying with the Statement. Thus, the total compliance burden is estimated to be approximately 125 burden-hours per year.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: April 6, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8793 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:
Regulation D and Form D, OMB Control No. 3235–0076, SEC File No. 270–072.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Regulation D (17 CFR 230.501 *et seq.*) sets forth rules governing the limited offer and sale of securities without Securities Act registration. The purpose of Form D (17 CFR 239.500) is to collect empirical data, which provides a continuing basis for action by the Commission either in terms of amending existing rules and regulations or proposing new ones. In addition, the Form D allows the Commission to elicit information necessary in assessing the effectiveness of Regulation D (17 CFR 230.501 *et seq.*) and Section 4(6) of the Securities Act of 1933 (15 U.S.C. 77d(6)) as capital-raising devices for all businesses. Approximately 25,000 issuers file Form D and it takes approximately 4 hours per response. We estimate that 25% of 4 hours per response (1 hour per response) is prepared by the issuer for an annual reporting burden 25,000 hours (1 hour per response × 25,000 responses). The remaining 75% of the burden is prepared by outside counsel.

Written comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: April 6, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8792 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66761; File No. SR–EDGX–2012–13]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to New EDGX Rule 11.22 Requiring Members To Input Accurate Information Into the System

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 2, 2012, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt new EDGX Rule 11.22 to require Members to input accurate information into the System,[3] including, but not limited to, identifying each order accurately as a principal, agency, or riskless principal order. The text of the proposed rule change is available on the Exchange's Web site at *www.directedge.com*, at the Exchange's principal office, and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add new EDGX Rule 11.22 for the purpose of increasing transparency and to enhance the surveillance database and audit trail of transaction data used by the Exchange in surveillance of its market. The proposed rule change would require Members to input accurate information into the System, including, but not limited to, identifying the capacity of each order accurately as a principal, agency, or riskless principal order. For purposes of surveillance, the Exchange currently identifies the capacity of each order as principal, agency, or riskless principal; however, several other capacities are accepted upon order entry, including no response, which are thereafter mapped to one of the above-listed order capacities. By requiring Members to accurately submit an order capacity for each order and to otherwise input accurate information into the System, the Exchange will be able to more precisely identify the type of order received and more effectively surveil for abusive trading.

EDGX does not currently have a rule that makes an explicit statement regarding a Member's obligation to input accurate information into the System. However, currently, in FIX tag 47,[4] Members are asked to populate their capacity when entering orders into the Exchange's System; however, if the field is left blank by the Member, it is automatically populated with an ''A'' value (denoting agency).

Notwithstanding, EDGX believes that disciplinary cases against Members entering inaccurate or incomplete information may be brought appropriately under EDGX Rule 3.1, which requires Members to observe high standards of commercial honor and just and equitable principles of trade. Rule 3.1 protects the investing public and the securities industry from dishonest practices that are unfair to investors or hinder the functioning of a free and open market, even though those practices may not be illegal or violate a specific rule or regulation. Because of the regulatory importance of inputting accurate information into the System, EDGX believes a rule that directly addresses Members' obligation to provide accurate information is warranted. The proposed rule makes clear Members' obligation to input accurate information into the System and that failure to do so would be considered a violation of EDGX Rules. In addition, once the rule is effective, if Members do not input the capacity in which they are acting (principal, agent, or riskless principal) into the System, the order will be rejected back to the Member by the Exchange.

EDGX notes that both BATS Exchange Inc. (''BATS'') and BATS–Y Exchange, Inc. (''BYX'') have adopted rules materially identical to proposed EDGX Rule 11.22.[5] Similarly, the Commission has previously approved rules proposed by the NASDAQ Stock Market LLC (''NASDAQ'') requiring participants to ensure that accurate information is entered into NASDAQ's system, including, but not limited to, the capacity in which the participant is acting.[6] Thus, the proposed rule change would bring EDGX Rules in line with those of other self-regulatory organizations.

In order to allow Members sufficient time to review and complete any systems changes necessitated by this filing, the Exchange will notify Members via information circular of an exact implementation date for the proposed rule change, which will be no later than August 31, 2012.

2. Statutory Basis

The rule change proposed in this submission is consistent with the requirements of Section 19(b)(1) of the Act[7] and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[8] Specifically, for the reasons described above, the proposed change is consistent with Section 6(b)(5) of the Act,[9] because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest. Specifically, the changes proposed herein will serve to promote the accuracy of information input into the Exchange. Accurate information is necessary for the efficient and fair operation of the Exchange, and will assist the Exchange in surveilling the markets for abusive or otherwise violative trading activity.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

---

[3] The term ''System'' is defined in EDGX Rule 1.5(cc).

[4] Members utilize an industry standard Financial Information eXchange (''FIX'') protocol to electronically enter orders into the System. Members populate certain FIX fields (*i.e.,* tags) to indicate certain terms of the order. FIX tag 47 is used to identify the Member's capacity.

[5] *See* Securities Exchange Act Release No. 63969 (February 25, 2011), 76 FR 12155 (March 4, 2011); and Securities Exchange Act Release No. 63970 (February 25, 2011), 76 FR 12204 (March 4, 2011).

[6] *See* Securities Exchange Act Release No. 59547 (March 10, 2009), 74 FR 11386 (March 17, 2009).

[7] 15 U.S.C. 78s(b)(1).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) of the Act [10] and paragraph (f)(6) of Rule 19b–4 thereunder.[11] The Exchange asserts that the proposed rule change: (1) Will not significantly affect the protection of investors or the public interest, (2) will not impose any significant burden on competition, and (3) will not become operative for 30 days from the date on which it was filed, or such shorter time as designated by the Commission. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing, or such shorter time as the Commission may designate.[12] In addition, the Exchange believes that the proposal to require Members to identify the capacity of each order as either a principal, agency, or riskless principal order does not present any policy issues that have not previously been considered by the Commission, but rather, is a minor change to the Exchange's existing rules that is consistent with the rules of other national securities exchanges.[13] For the foregoing reasons, this rule filing qualifies for immediate effectiveness as a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGX–2012–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2012–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2012–13 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8785 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4 (f)(6).

[12] 17 CFR 240.19b–4 (f)(6)(iii).

[13] *See, e.g.,* NASDAQ Rule 4611(a)(6), BATS Rule 11.21 and BYX Rule 11.21.

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66763; File No. SR–EDGA–2012–13]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the EDGA Exchange, Inc. Fee Schedule

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2012 the EDGA Exchange, Inc. (the ''Exchange'' or the ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its fees and rebates applicable to Members [3] of the Exchange pursuant to EDGA Rule 15.1(a) and (c). All of the changes described herein are applicable to EDGA Members. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.directedge.com,* at the Exchange's principal office, and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Member is any registered broker or dealer, or any person associated with a registered broker or dealer, that has been admitted to membership in the Exchange.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to decrease the rebate for adding liquidity from $0.0004 per share to $0.0003 per share, and to decrease the rebates in Footnote 4 in the fee schedule from $0.0005 per share to $0.0004 per share as they relate to the calculation for the Total Consolidated Volume (''TCV'') in order to move in lockstep with the proposed rebate of $0.0003 per share for adding liquidity. In addition, the Exchange proposes to make conforming amendments on Flags B, V, Y, 3 and 4 from a rebate of $0.0004 per share to a rebate of $0.0003 per share.

Flag E represents a customer internalization [4] charge per side if a Member inadvertently matches with itself. In order to provide additional transparency to Members, Flag E is proposed to be bifurcated into two flags: Flag EA (internalization on the adding liquidity side) and Flag ER (internalization on the removing liquidity side). The Exchange also proposes to increase the fee charged to Members to $0.0002 per share, per side, to move in lockstep with the maker/taker spread on EDGA, which the Exchange proposes to change to $0.0004. Similarly, the Exchange also proposes increasing the charge assessed in Flag 5 from $0.00015 to $0.0002.

The Exchange proposes to add Flag PR for orders that remove liquidity from EDGA using eligible routing strategies ROUZ, ROUD or ROUQ.[5] The Exchange proposes to list the eligible routing strategies in Footnote 15. The Exchange proposes to assess no charge to Members that utilize Flag PR. Therefore, the Exchange proposes to append Footnote 1 to Flag PR so that the Members using Flag PR will also be subject to the conditions of Footnote 1, which state that the removal rate on EDGA is contingent on the attributed MPID adding (including hidden) and/or routing a minimum average daily share volume, measured monthly, of 50,000 shares on EDGA. Any attributed MPID not meeting the aforementioned minimum will be charged $0.0030 per share for removing liquidity from EDGA for securities priced $1.00 and over and 0.20% of dollar value for securities priced less than $1.00.

The Exchange proposes to add Flag CR for orders that remove liquidity from EDGA using eligible routing strategies ROUT, RDOT, ROUE, ROUC, ROOC, ROCO, IOCT or ICMT.[6] The Exchange proposes to list the eligible routing strategies in Footnote 13. The Exchange proposes to assess no charge to Members that utilize Flag CR. Therefore, the Exchange proposes to append Footnote 1 to Flag CR so that Member's using Flag CR will also be subject to the conditions of Footnote 1, which states that the removal rate on EDGA is contingent on the attributed MPID adding (including hidden) and/or routing a minimum average daily share volume, measured monthly, of 50,000 shares on EDGA. Any attributed MPID not meeting the aforementioned minimum will be charged $0.0030 per share for removing liquidity from EDGA for securities priced $1.00 and over and 0.20% of dollar value for securities priced less than $1.00.

The Exchange proposes to add Flag XR for orders that remove liquidity from EDGA using eligible routing strategies ROUX, RDOX, ROPA, INET, ROBB, ROBY, ROBX, ROBA, SWPA, SWPB, SWPC, ROLF, IOCX or IOCM.[7] The Exchange proposes to list the eligible routing strategies in Footnote 14. The Exchange proposes to assess a charge of $0.0007 per share to Members that utilize Flag XR, which corresponds to the default rate on EDGA for removing liquidity. Therefore, the Exchange proposes to append Footnote 1 to Flag XR so that Member's using Flag XR will also subject to the conditions of Footnote 1, which states that the removal rate on EDGA is contingent on the attributed MPID adding (including hidden) and/or routing a minimum average daily share volume, measured monthly, of 50,000 shares on EDGA. Any attributed MPID not meeting the aforementioned minimum will be charged $0.0030 per share for removing liquidity from EDGA for securities priced $1.00 and over and 0.20% of dollar value for securities priced less than $1.00.

The Exchange proposes to amend the description of Flag K in reference to orders routed to the PSX to include the ROUE routing strategy in addition to the ROUC routing strategy. The Exchange proposes to continue to assess a charge of $0.0025 per share.

Similarly, the Exchange proposes to amend the description of Flag BY in reference to orders routed to the BATS BYX Exchange to include the ROUE routing. The Exchange proposes to continue to offer a rebate of $0.0002 per share.

Currently, when an order is routed using the ROUQ or ROUC routing strategies, as defined in Rule 11.9(b)(3), a fee of $0.0020 per share is charged. The Exchange proposes to append footnote 16 to the Q flag to provide a lower rate for Q flag executions in the following circumstances: If a Member posts greater than or equal to 0.30% of the TCV in ADV on EDGA and routes 2.5 million shares through the use of the Q flag, then the Member's rate for the Q flag decreases to $0.0015 per share. If a Member posts greater than or equal to 0.30% of the TCV in ADV on EDGA and routes 5 million shares through the use of the Q flag, then the Member's rate for the Q flag decreases to $0.0010 per share.

The Exchange also proposes to make a technical amendment to Footnote 1 on the fee schedule to remove ''the'' and replace it with ''all,'' remove ''is'' and replace it with ''are,'' and pluralize ''rate.'' In addition, the Exchange also proposes to make a technical amendment to remove the word ''customer'' in the description of Flag 5.

The Exchange proposes to implement these amendments to its fee schedule on April 1, 2012.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with the objectives of Section 6 of the Act,[8] in general, and furthers the objectives of Section 6(b)(4),[9] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

The Exchange proposes to decrease the rebate for adding liquidity from $0.0004 per share to $0.0003 per share, and to decrease the rebate in Footnote 4 in the fee schedule from $0.0005 per share to $0.0004 per share as they relate to the calculation for the TCV in order to move in lockstep with the proposed rebate of $0.0003 per share for adding liquidity. In addition, the Exchange will make corresponding changes to Flags B, V, Y, 3 and 4 because these Flags also add liquidity to the EDGA book. In addition, the increased revenue to the Exchange from the decreased rebate allows the Exchange to have additional revenue to offset administrative and infrastructure costs, and to offset the no charge for Flags PR and CR as described

[4] This occurs when two orders presented to the Exchange from the same Member (i.e., MPID) are presented separately and not in a paired manner, but nonetheless inadvertently match with one another. Members are advised to consult Rule 12.2 respecting fictitious trading.

[5] *See* Exchange Rule 11.9(b)(3).

[6] *Id.*

[7] *Id.*

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

below. The Exchange believes that the proposed rate is non-discriminatory in that it applies uniformly to all Members.

The Exchange believes that the proposed technical amendment to delete Flag E and replace it with Flags EA and ER promotes market transparency and improves investor protection by adding additional transparency to its fee schedule by more precisely delineating for Members whether they are ''adders of liquidity'' or ''removers of liquidity'' for purposes of paying an internalization fee. Similarly, the Exchange also proposes increasing the charge assessed in Flag 5 from $0.00015 to $0.0002 because it pertains to internalization. In addition, the internalization rebate is equitable in that it is in line with the EDGA fee structure [10] which currently has a maker/taker spread of $0.0004 per share (the proposed standard rebate to add liquidity on EDGA is $0.0003 per share, while the standard fee to remove liquidity is $0.007 per share). EDGA also has a proposed tiered rate for adding liquidity of $0.0004, which would make this spread $0.0003 per share. As a result of the internalization charge, Members who internalize would be charged $0.0002 per side of an execution (total of $0.0004 per share) instead of capturing the maker/taker spread of $0.0003 per share if Members achieve this tier. Therefore, the total net amount equals $0.0004 per share, which would be an internalization rate that is no more favorable than the prevailing maker/taker spread. The Exchange also believes that the proposal is non-discriminatory because it applies to all Members.

The Exchange proposes to add Flag PR for orders that remove liquidity from EDGA using eligible routing strategies ROUZ, ROUD or ROUQ. The Exchange believes that the proposed rate of $0.0000 per share for Flag PR is an equitable allocation of reasonable dues, fees, and other charges because the rate correlates to the dues, fees, and other charges the Exchange receives when routing to low cost destinations. By routing to several low cost destinations using the eligible routing strategies, there is a greater potential for orders to be executed at these low cost destinations rather than a higher cost destination. For example, ROUD, as defined in Rule 11.9(b)(3)(b), is a routing option under which an order checks the System [11] for available shares and then is sent sequentially to low cost destinations on the System routing table. Therefore, the more low cost destinations that an order routes to allows the Exchange to pass on the savings it receives from such destinations to the Exchange's Members. In addition, the Exchange believes that the proposed rate is non-discriminatory in that it applies uniformly to all Members.

The Exchange proposes to add Flag CR for orders that remove liquidity from EDGA using eligible routing strategies ROUT, RDOT, ROUE, ROUC, ROOC, ROCO, IOCT or ICMT, which route to a combination of low cost destinations and higher cost destinations. The Exchange believes that the proposed rate of $0.0000 per share for Flag CR is an equitable allocation of reasonable dues, fees, and other charges because the rate correlates to the dues, fees, and other charges the Exchange receives when routing to low cost destinations. By routing to several low cost destinations using the eligible routing strategies, there is a greater potential for orders to be executed at these low cost destinations. For example, RDOT, as defined in Rule 11.9(b)(3)(h), is a routing option under which an order checks the System for available shares and then is sent sequentially to low cost destinations on the System routing table. If shares remain unexecuted after routing, they are sent to the NYSE and can be re-routed by the NYSE, which is a high cost destination. Therefore, the more low cost destinations that an order routes to allows the Exchange to pass on the savings it receives from such destinations to the Exchange's Members. In addition, the Exchange believes that the proposed rate is non-discriminatory in that it applies uniformly to all Members.

In addition, the Exchange believes its proposed rate of $0.0000 per share for Flags PR and CR is equitable because Flags PR and CR both route to low cost destinations in the System.

The Exchange proposes to add Flag XR for orders that remove liquidity from EDGA using eligible routing strategies ROUX, RDOX, ROPA, INET, ROBB, ROBY, ROBX, ROBA, SWPA, SWPB, SWPC, ROLF, IOCX or IOCM. The Exchange believes that the proposed rate of $0.0007 per share for Flag XR which corresponds to the default rate on EDGA for removing liquidity, is an equitable allocation of reasonable dues, fees, and other charges because the rate is directly correlated with a higher number of high cost destinations; therefore, Flag XR creates a greater potential for an execution at a higher cost destination. For example, ROPA, as defined in Rule 11.9(b)(3)(k), is a routing option under which an order checks the System for available shares and then is sent, as an immediate or cancel (IOC) order, to NYSE Arca, which is a higher cost destination. Therefore, the Exchange passes through the charges associated with such higher cost destinations to the Exchange's Members. The Exchange believes that the proposed rate is non-discriminatory in that it applies uniformly to all Members.

The Exchange proposes to amend the description of Flag K in reference to orders routed to the PSX to include the ROUE routing strategy in addition to the ROUC routing strategy. The Exchange proposes to continue to assess a charge of $0.0025 per share. The Exchange believes that including the ROUE routing strategy will benefit Members because it provides another routing strategy to earn Flag K. In addition, the Exchange offers Members additional transparency in the fee schedule because Members can identify the routing strategy used to achieve Flag K. This encourages Members to utilize the Exchange to route to various destinations, which results in a lower overall routed rate for Members and allows the Exchange to pass on the savings it receives to the Exchange's Members. The Exchange believes that the proposed rebate is non-discriminatory in that it applies uniformly to all Members.

Similarly, the Exchange proposes to amend the description of Flag BY in reference to orders routed to the BATS BYX Exchange to include the ROUE routing strategy. The Exchange proposes to continue to offer a rebate of $0.0002 per share. The Exchange believes that including the ROUE routing strategy will benefit Members because it provides another routing strategy to earn Flag BY. In addition, the Exchange offers Members additional transparency in the fee schedule because Members can identify the routing strategy used to achieve Flag BY. This encourages Members to utilize the Exchange to route to various destinations, which results in a lower overall routed rate for Members and allows the Exchange to pass on the savings it receives to the Exchange's Members. The Exchange believes that the proposed rebate is non-discriminatory in that it applies uniformly to all Members.

The Exchange believes that the lower rate on the Q flag if a Member satisfies the conditions in proposed footnote 16 of the fee schedule represents and equitable allocation of reasonable dues, fees, and other charges as it is designed to incentivize Members to utilize the

[10] In SR–EDGA–2011–14 (April 29, 2011), the Exchange represented that it ''will continue to ensure that the internalization fee is no more favorable than each prevailing maker/taker spread.''

[11] *See* Exchange Rule 1.5(cc).

routing strategies on flag Q (ROUQ/ROUC) to route through EDGA before routing to other low cost destinations and other venues. If a Member does so and adds a significant amount of liquidity to EDGA (posts greater than or equal to 0.30% of the TCV in ADV on EDGA), while at the same time routes through ROUQ or ROUC a certain number of shares (2.5 million or 5 million shares), then the Member's rate will decrease to $0.0015 per share or $0.0010 per share, depending on the amount of liquidity routed using the ROUQ or ROUC routing strategies. The Exchange believes that volume discounts such as the ones proposed herein increases potential revenue to the Exchange, and would allow the Exchange to spread its administrative and infrastructure costs over a greater number of shares, leading to lower per share costs. These lower per share costs would allow the Exchange to pass on the savings to Members in the form of lower rates. The increased liquidity also benefits all investors by deepening EDGA's liquidity pool, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. Volume-based discounts such as the ones proposed herein have been widely adopted in the cash equities markets, and are equitable because they are open to all Members on an equal basis and provide discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and introduction of higher volumes of orders into the price and volume discovery processes. In addition, the rates on the flag Q are reasonable when compared to competitive strategies on BATS, the DRT strategy [12], which is priced at $0.0020 per share and is similar to ROUQ; the ROUC routing strategy is similar to BATS's SLIM strategy [13] (rates ranging from $0.0022 per share to $0.0029 per share) and to NASDAQ's SAVE/SOLV strategies[14] (rates ranging from $0.0022 per share to $0.0027 per share).

The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act [15] and Rule 19b 4(f)(2) [16] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGA–2012–13 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2012–13. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2012–13 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8787 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[12] *See* the BATS BZX and BATS BYX Fee Schedules, http://batstrading.com/FeeSchedule

[13] *Id.*

[14] *See* NASDAQ Price List, *http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2*

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 19b 4(f)(2) [sic].

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66769; File No. SR–CBOE–2012–033]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to FLEX Options

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2012, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared by the Exchange. The Exchange has designated the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to provide for additional time to implement new system enhancements for trading Flexible Exchange Options (''FLEX Options'') [5] that were the subject of another rule change filing that was recently approved. No changes to the rule text are necessary with respect to this revised implementation plan. The Exchange is also proposing to make certain amendments to its rules for trading FLEX Options. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/legal*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 7, 2012, the Exchange received approval of a rule change filing, SR–CBOE–2011–122, which amended certain rules pertaining to the electronic trading of FLEX Options on the Exchange's FLEX Hybrid Trading System platform (the ''FLEX System'' or ''System'').[6] In that filing, the Exchange indicated that it is in the process of enhancing the FLEX System in order to further integrate it with the Exchange's existing technology platform utilized for Non-FLEX trading. In conjunction with the enhancement, the filing made some modifications to the existing electronic trading processes utilized on the FLEX System platform. The filing made other amendments to eliminate certain European-Capped style settlement and currency provisions with the FLEX rules that pertain to both electronic and open outcry trading. The filing also indicated that the Exchange planned to announce to its Trading Permit Holders (''TPHs'') via Regulatory Circular an implementation schedule for transitioning from the existing technology platform to the new technology platform once the rollout schedule is finalized. The filing indicated that the Exchange intended to begin implementation by no later than March 30, 2012, with the specific implementation schedule to be announced via Regulatory Circular, as stated above. The Exchange intended to transition a few classes at a time and anticipated full implementation within approximately one to three weeks of the initial transition. Finally, in the event that implementation did not begin by March 30, 2012, the Exchange represented that it would file a proposed rule change to establish the revised time period.

The Exchange has determined that it needs some more time to implement the FLEX System enhancements. Therefore, in accordance with rule change filing SR–CBOE–2011–122, the Exchange is submitting this instant proposed rule change filing to establish a revised time period. Rather than March 30, 2012, the Exchange now intends to begin implementation by no later than April 30, 2012, with the specific implementation schedule to be announced via Regulatory Circular. The Exchange still intends to transition a few classes at a time and anticipates full implementation within approximately one to three weeks of the initial transition. Consistent with the prior rule change filing, in the event the implementation does not begin by April 30, 2012, the Exchange represents that it will file another proposed rule change to establish the revised time period.

The Exchange is also proposing to take this opportunity to make certain other changes to the FLEX rules. First, as noted above, in rule change filing SR–CBOE–2011–122 the Exchange deleted references to certain European-Capped style settlement and foreign currency provisions (and related index multiplier provisions for such currencies).[7] The European-Capped style and foreign currency provisions have generally not been actively utilized.[8] Since the Exchange no longer plans to support foreign currency settlements in the new FLEX System, the Exchange limited the currency for FLEX Index Options to U.S. dollars.[9] Because the European-Capped style exercise and foreign currency provisions are no longer applicable, the Exchange is now proposing to delete certain other superfluous and unnecessary references to European-Capped style exercise

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] FLEX Options provide investors with the ability to customize basic option features including size, expiration date, exercise style, and certain exercise prices. FLEX Options can be FLEX Index Options or FLEX Equity Options. In addition, other products are permitted to be traded pursuant to the FLEX trading procedures. For example, credit options are eligible for trading as FLEX Options pursuant to the FLEX rules in Chapters XXIVA and XXIVB. *See* CBOE Rules 24A.1(e) and (f), 24A.4(b)(1) and (c)(1), 24B.1(f) and (g), 24B.4(b)(1) and (c)(1), and 28.17. The rules governing the trading of FLEX Options on the FLEX Request for Quote (''RFQ'') System platform (which is limited to open outcry trading only) are contained in Chapter XXIVA. The rules governing the trading of FLEX Options on the FLEX Hybrid Trading System platform (which combines both open outcry and electronic trading) are contained in Chapter XXIVB. The Exchange notes that, currently, all FLEX Options are traded on the FLEX Hybrid Trading System platform.

[6] Securities Exchange Act No. 66348 (February 7, 2012), 77 FR 8304 (February 14, 2012) (SR–CBOE–2011–122).

[7] Specifically, the Exchange eliminated references to European-capped style settlement and foreign currency provisions (and related index multiplier provisions) that were formerly contained in Rules 24A.1(c) and (i), 24A.4(a)(2)(iii) and (b)(4), 24A.5(f), 24B.1(c) and (m), 24B.4(a)(2)(iii) and (b)(4), and 24B.5(e).

[8] The Exchange notes that there is currently no open interest in any FLEX Option series with a European-Capped style exercise and currently no open interest in any FLEX Index Option series that is designated for settlement in a foreign currency.

[9] In the future, the Exchange may determine to re-enable the capability for settlement of FLEX Index Options in a foreign currency, and such foreign currency settlement provisions would be the subject of a separate rule filing.

options contained elsewhere in Rules 24A.4(b)(2) and 24B.4(b)(2) and to currencies (and related index multiplier provisions for currencies) contained elsewhere in Rules 24A.1(i), (o) and (q), 24A.4(a)(1) and (3)(i), 24A.9(a), 24B.1(m), (w) and (z), 24B.4(a)(1), (3)(i) and (4)(i), and 24B.9(a) and (b).

Second, the Exchange is proposing to amend Rules 24B.1(n) and 24B.14(b) and (c) to delete references to Indicative FLEX Quotes. An ''Indicative FLEX Quote'' refers to informational FLEX bids and offers submitted electronically by FLEX Traders in response to a call for such quotes from the FLEX Post Official or a FLEX Trader. Indicative FLEX Quotes are non-binding indications of potential market prices only and, as such, are neither firm nor the basis for a FLEX transaction. Under the existing procedures, a FLEX Official [10] may call for such Indicative FLEX quotes at any time during the course of trading and with respect to any series of FLEX Options that the FLEX Official deems appropriate. In addition, FLEX Traders [11] may call for Indicative FLEX Quotes, updates thereto, or cancellations thereof. FLEX Traders could electronically communicate their Indicative FLEX Quotes and the information would be disseminated over the FLEX Hybrid Trading System communications network interface. This functionality generally has not been utilized and the Exchange has determined that it will no longer be supported when trading begins on the enhanced System (the new System does not have a similar communication network interface), so the Exchange is proposing to delete the definition of an Indicative FLEX Quote in Rule 24B.1 and the procedures noted in Rule 24B.14.[12]

Third, the Exchange is proposing to amend Rules 24A.4, 24B.1, 24B.4 and 24B.5 to revise some references to FLEX Terms and Trade Conditions, which are no longer utilized and will not be supported by the Exchange going forward. Specifically:

- The current Trade Conditions available in the System for a FLEX Trader to choose from are described in Rule 24B.1(y) and include Immediate-or-Cancel (a condition to execute a RFQ Order or FLEX Quote in its entirety or in part as soon as it is represented or cancel it), All-or-None (a condition to execute an RFQ Order or FLEX Order in its entirety or not at all) and Hedge (an RFQ or FLEX Order condition contingent on trade execution in Non-FLEX Options or other Non-FLEX components (*e.g.,* stock, futures, or other related instruments or interests)).[13] These Trade Conditions only apply to electronic trading (not open outcry). Therefore, although the rule text already provides that these Trade Conditions are only available in the System and describes whether or not they are disclosed in the System, the Exchange is proposing to include certain references to ''electronic RFQs'' to make it more clear that the provisions only apply to electronic trading. In addition, the Exchange is proposing to delete the All-or-None Trade Condition because the System will no longer support the electronic processing of the All-or-None Trade Condition for electronic RFQ Orders or FLEX Orders. (Through a separate rule change filing, the Exchange is seeking to introduce an electronic FLEX Solicitation Auction Mechanism (the ''FLEX SAM'' auction) under proposed new Rule 24B.5B that will have an all-or-none type functionality).[14]

- Rule 24B.5(d)(2)(i) provides that the Exchange may from time to time establish a crossing participation entitlement subject to certain conditions. Previously, this provision described conditions with respect to both open outcry RFQ crossing participation entitlements and electronic RFQ crossing participation entitlements. However, in rule change filing SR–CBOE–2011–122, the Exchange eliminated the Intent to Cross Trade Condition[15] and related references to a crossing participation entitlement for electronic RFQs in various provisions, including certain references in Rule 24B.5(d)(2)(i)(A) and (B). Given the elimination of these provisions, the Exchange is proposing to delete a superfluous and unnecessary reference to the ''BBO clearing price'' in paragraphs (A) and (B). The Exchange is proposing to delete these references because the ''BBO clearing price'' references in paragraphs (A) and (B) were/are only applicable to electronic RFQs and were/are not applicable to open outcry RFQs. (Under the former electronic RFQ procedures, a Submitting TPH could have obtained a crossing participation entitlement if, among other things, the TPH matched or improved the BBO clearing price.) The Exchange is also proposing to delete a superfluous and unnecessary reference contained in Rule 24B.5(d)(2)(i)(C) to a Submitting TPH utilizing the electronic RFQ mechanics to cross an order with a solicited order for a FLEX Market-Maker account (or with a solicited order initiated by a FLEX Market-Maker for an account in which the FLEX Market-Maker has in interest) pursuant to the crossing participation entitlement provisions under Rule 24B.5(d)(2)(i)(A) and (B). Again, the Exchange is proposing to delete these references in paragraph (C) because the electronic RFQ crossing participation entitlement provisions have been eliminated from the rules.

- Currently, the terms of a FLEX RFQ shall contain, among other things, specifications on the quote type and form sought (*i.e.,* specify whether bid, offer, or both is sought). The Exchange is proposing to amend the rules to provide that an open outcry RFQ can specify a quote for a bid, offer or both; however, electronic RFQs will be limited to specifying both bids and offers. Therefore, the Exchange is proposing to amend the provision in

[10] The Exchange may at any time designate an Exchange employee or independent contractor to act as a FLEX Official in one or more classes of FLEX Options. A FLEX Official performs the functions set out in Rule 24B.14.

[11] The reference to ''FLEX Traders'' includes any TPHs that have been approved by the Exchange to use the FLEX Hybrid Trading System and any non-TPH Sponsored Users that have been provided electronic access, through Sponsoring TPHs, to the FLEX Hybrid Trading System in accordance with Rule 6.20A, *Sponsored Users.*

[12] Over the years, Exchange has offered an Indicative FLEX Quote service, then discontinued the service, then reinstated it, and is now seeking to discontinue the service because it continues to not be actively utilized. See, e.g., Securities Exchange Act Release No. 58719 (October 2, 2008), 73 FR 59692 (October 9, 2008) (SR–CBOE–2008–103). In the future, the Exchange may determine to offer an Indicative FLEX Quote service and such a service would be the subject of a separate rule filing.

[13] An ''RFQ'' refers to a Request for Quotes, which means an initial request supplied by a Submitting TPH to initiate FLEX bidding and offering. An ''RFQ Order'' is an order to purchase or order to sell FLEX Options entered by the Submitting TPH during the RFQ Reaction Period. The ''RFQ Reaction Period'' is the period of time during which a Submitting TPH determines whether to accept or reject the RFQ Market (which is currently defined as the bids or offers, or both, as applicable, entered in response to an electronic RFQ and FLEX Orders resting in the electronic book). A FLEX Order refers to (i) FLEX bids and offers entered by FLEX Market-Makers and (ii) orders to purchase or sell FLEX Options entered by FLEX Traders, in each case into the electronic book. *See* Rule 24B.1(j), (r)–(t), (v).

[14] *See* Securities Exchange Act Release No. 66052 (December 23, 2011), 77 FR 306 (January 4, 2012)(SR–CBOE–2011–123). In SR–CBOE–2011–123, the Exchange is proposing to adopt new Rule 24B.5A (pertaining to the FLEX Automated Improvement Mechanism or ''FLEX AIM'' auction) and new Rule 24B.5B (pertaining to the FLEX SAM auction). The FLEX SAM would be used to cross FLEX Option orders through an exposed auction process. An original agency order and paired contra-side order entered into the SAM Auction would also be designated in the FLEX System as all-or-none (*i.e.,* an order will be executed in its entirety or not at all).

[15] ''Intent to Cross'' was an RFQ condition indicating that the Submitting TPH intends to cross or act as principal and receive a crossing participation entitlement. *See* former Rule 24B.1(y)(5).

Rules 24B.4(a)(3) and definition of RFQ Market in Rule 24B.1(s).[16]

• Under the current special terms for FLEX Index Options, exercise prices shall be specified in terms of a specific index value number, a method of fixing such a number at the time a FLEX Quote is accepted, or a percentage of index value calculated as of the open or close of trading on the Exchange on the trade date. The Exchange is proposing to delete the reference to a percentage of the index value calculated as of the open of trading on the Exchange on the trade date. This provision has generally not been actively utilized[17] and will no longer be supported when trading begins on the enhanced System. Therefore, the Exchange is proposing to delete the provision under Rules 24A.4(b)(2) and 24B.4(b)(2).

• Under the current special terms for FLEX Equity Options, exercise prices may be rounded to the nearest minimum tick, one-eighth of a dollar, or other decimal increment determined by the Exchange on a class-by-class basis that may not be smaller than $0.01. The Exchange is proposing to delete the reference to nearest one-eighth of a dollar. This language used to be applicable when the Exchange traded in fractional increments and there was open interest in series with exercise prices in such an increment. However, there are no longer any options with exercise prices in this increment, so the Exchange is proposing to delete the ''one-eighth of a dollar'' language under Rules 24A.4(c)(2) and 24B.4(c)(2).

Finally, the Exchange is proposing to amend Rules 24B.3, 24B.5 and 24B.9 to revise some of the descriptions of the electronic RFQ trading procedures. Specifically:

• Currently, Rule 24B.3 provides that there shall be no trading rotations in FLEX Options, either at the opening or at the close of trading. An existing FLEX Option series will automatically open for trading at a randomly selected time within a number of seconds after 8:30 a.m. (all times are CT), at which point FLEX Orders may be entered directly into the electronic book (if available) and/or FLEX RFQ auctions may be initiated pursuant to Rule 24B.5. A new FLEX Option series may be established on any business day prior to the expiration date as provided for in Rule 24A.4 and opened for trading pursuant to the procedures and principles as provided for in Rule 24B.5. The Exchange is proposing to amend Rules 24B.3 and 25B.5 to make clear that, besides RFQs under Rule 24B.5, auctions may also be initiated in existing and new series pursuant to proposed new Rule 24B.5A (regarding FLEX AIM auctions) or proposed new Rule 24B.5B (regarding FLEX SAM auctions).[18]

• Currently the electronic RFQ process in relevant part provides in Rule 24B.5(a)(1)(ii) and (iii) that FLEX Orders may be entered, modified or withdrawn at any point during the RFQ Response and Reaction Periods.[19] When trading moves to the enhanced System, FLEX Orders may not be submitted to electronic book during the RFQ Response Period, but may be withdrawn. If a FLEX Trader attempts to enter a FLEX Order during the RFQ Response and Reaction Periods, the FLEX Order will be rejected by the System. Therefore, the Exchange is proposing to amend Rule 24B.5(a)(1)(ii) and (iii) to describe how FLEX Orders will be handled under the enhanced System. The Exchange is also proposing to delete references in these provisions indicating that FLEX Quotes may be modified during the RFQ Response and Reaction Periods (mechanically, FLEX Quotes submitted in response to an electronic RFQ may only be modified by withdrawing FLEX Quotes and entering new FLEX Quotes).[20] The Exchange is also proposing to amend Rule 24B.9 to make clear that FLEX Quotes submitted in response to an electronic RFQ by FLEX Market-Makers shall be entered or withdrawn within the RFQ Response and Reaction Periods, which is consistent with Rule 24B.5(a)(1)(ii) and (iii).

• Currently the electronic RFQ process provides that, if there is an electronic book available, any remaining balance of FLEX Quotes not traded at the conclusion of the RFQ Reaction Period will be automatically entered into the electronic book (and treated the same as other FLEX Orders) unless the FLEX Trader has indicated that the FLEX Quote is to be automatically cancelled if not traded. When trading moves to the enhanced System, any remaining balance of FLEX Quotes will be automatically cancelled at the conclusion of the RFQ Reaction Period. Therefore, the Exchange is proposing to amend Rule 24B.5(a)(iii)(E) (and to delete a related cross-reference in Rule 24B.5(b)(1)) to describe how any remaining balance of FLEX Quotes will be handled under the enhanced System.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act[21] in general and furthers the objectives of Section 6(b)(5) of the Act[22] in particular in that it should promote just and equitable principles of trade, serve to remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. In particular, the Exchange believes that the use of FLEX Options provides CBOE TPHs and investors with additional tools to trade customized options in an exchange environment[23] and greater opportunities to manage risk. The Exchange believes that the enhancements to the FLEX System adopted under rule change filing SR–CBOE–2011–122 should serve to further those objectives and encourage use of FLEX Options by enhancing and simplifying the existing processes and integrating the FLEX System with the

[16] As revised, the term ''RFQ Market'' will mean the bids and offers entered in response to an electronic RFQ and FLEX Orders resting in the electronic book. *See* proposed changes to Rule 24B.1(s); *see also* note 13, *supra,* for current definition of ''RFQ Market.''

[17] The Exchange notes that there is currently no open interest in any FLEX Index Option series with an exercise price specified in terms of a percentage of the index value calculated as of the open of trading on the Exchange on the trade date.

[18] Thus, as revised, the text of Rule 24B.3 will provide in relevant part that an existing series will automatically open for trading at a randomly selected time within a number of seconds after 8:30 a.m. (all times are CT), at which point FLEX Orders may be entered directly into the electronic book (if available) and/or a FLEX auction may be initiated pursuant to Rule 24B.5, 24B.5A, or 24B.5B. A new FLEX Option series may be established on any business day prior to the expiration date as provided for in Rule 24A.4 and opened for trading pursuant to the procedures and principles as provided for in Rule 24B.5, 24B.5A or 24B.5B. See proposed changes to Rule 24B.3; *see also* proposed changes to Rule 24B.5(a), and SR–CBOE–2011–123, note 14, *supra.*

[19] The ''RFQ Response Period'' (commonly referred to as ''T1'') means the period of time during which FLEX Traders may provide FLEX Quotes in response to an RFQ. As noted in note 13, *supra,* the ''RFQ Reaction Period'' (commonly referred to as ''T2'') means the period of time during which a Submitting TPH determines whether to accept or reject the RFQ Market. See Rule 24A.1(u)–(v).

[20] The Exchange also proposes to replace a reference to the FLEX Book with a reference to the electronic book in Rule 24B.5(d)(1).

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] FLEX Options provide TPHs and investors with an improved but comparable alternative to the over-the-counter (''OTC'') market in customized options, which can take on contract characteristics similar to FLEX Options but are not subject to the same restrictions. The Exchange believes that making these changes will make the FLEX Hybrid Trading System an even more attractive alternative when market participants consider whether to execute their customized options in an exchange environment or in the OTC market. CBOE believes market participants benefit from being able to trade customized options in an exchange environment in several ways, including, but not limited to the following: (1) Enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of The Options Clearing Corporation as issuer and guarantor of FLEX Options.

Exchange's existing technology platform for Non-FLEX trading, which should make the FLEX System more efficient and effective and easier for users to understand. The Exchange believes that the further refinements being proposed in this instant rule change filing should also serve to further those objectives by more clearly and accurately describing the operation of the enhanced System and deleting superfluous and unnecessary provisions in the FLEX rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited or received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [24] and Rule 19b–4(f)(6) thereunder.[25] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[26]

A proposed rule change filed under Rule 19b–4(f)(6) [27] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[28] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because such waiver will allow CBOE to codify the revisions to its rules to more clearly and accurately describe the operation of its new system for FLEX Options prior to implementation. Therefore, the Commission designates the proposal operative upon filing.[29]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2012–033 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2012–033. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2012–033 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8839 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66768; File No. SR–NASDAQ–2012–048]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Customer Fees and Rebates in Penny Pilot Options

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 2, 2012, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASDAQ. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

---

[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 240.19b–4(f)(6)(iii).

[29] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes to modify Chapter XV, entitled ''Option Pricing,'' at Section 2 governing pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options. Specifically, NOM proposes to amend the Penny Pilot [3] Options (''Penny Options'') Customer Rebates to Add Liquidity and Penny Options Customer Fee for Removing Liquidity. The Exchange also proposes to make other minor amendments to the Section 2.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ proposes to modify Chapter XV, entitled ''Option Pricing,'' at Section 2 governing the rebates and fees assessed for option orders entered into NOM. Specifically, the Exchange is proposing to modify the five tier structure for paying Customer Rebates to Add Liquidity in Penny Options. The Exchange proposes to amend various rebate tiers to further incentivize NOM Participants to route Customer orders in Penny Options to the Exchange by paying additional rebates for certain orders after the NOM Participant has met a volume criteria and also removing certain criteria to qualify for a rebate. The Exchange believes that incentivizing NOM Participants to send additional Customer orders in Penny Options to the Exchange will benefit all market participants by adding liquidity to the market.

Specifically, the Exchange currently pays a Customer Rebate to Add Liquidity in Penny Options based on the following tier structure:

* * * The Customer Rebate to Add Liquidity in Penny Pilot Options will be paid as noted below. Each Customer order of 5,000 or more, displayed or non-displayed contracts, which adds liquidity in Penny Pilot Options, will qualify for an additional rebate of $0.01 per contract provided the NOM Participant has qualified for a rebate in Tier 2, 3, 4 or 5 for that month.

Monthly volume	Rebate to add liquidity
Tier 1 Participant adds Customer liquidity of up to 14,999 contracts per day in a month	$0.26
Tier 2 Participant adds Customer liquidity of 15,000 to 49,999 contracts per day in a month	0.38
Tier 3 Participant adds Customer liquidity of 50,000 or more contracts per day in a month	0.42
Tier 4 [a] Participant adds (1) Customer liquidity of 100,000 or more contracts per day in a month, and (2) NOM Market Maker liquidity of 40,000 or more contracts per day in a month	0.43
Tier 5 [b] Participant adds (1) Customer liquidity of 25,000 or more contracts per day in a month, (2) the Participant has certified for the Investor Support Program set forth in Rule 7014; and (3) the Participant executed at least one order on NASDAQ's equity market	0.41

[a] For purposes of Tier 4, the Exchange will aggregate the trading activity of separate NOM Participants when computing average daily volumes where 75 percent common ownership or control exists between NOM Participants.

[b] For purposes of Tier 5, the Exchange will allow a NOM Participant to qualify for the rebate if a NASDAQ member under common ownership with the NOM Participant has certified for the Investor Support Program and executed at least one order on NASDAQ's equity market. Common ownership is defined as 75 percent common ownership or control.

The Exchange proposes to amend the tier structure for Customer Rebates to Add Liquidity in Penny Options as follows:

* * * The Customer Rebate to Add Liquidity in Penny Pilot Options will be paid as noted below. Each Customer order of 5,000 or more, displayed or non-displayed contracts, which adds liquidity in Penny Pilot Options, will qualify for an additional rebate of $0.01 per contract provided the NOM Participant has qualified for a rebate in Tier 2, 3, 4 or 5 for that month.

Monthly volume	Rebate to add liquidity
Tier 1 Participant adds Customer liquidity of up to 14,999 contracts per day in a month	$0.26
Tier 2 Participant adds Customer liquidity of 15,000 to 49,999 contracts per day in a month	0.38
Tier 3 Participant adds Customer liquidity of 50,000 to 74,999 contracts per day in a month	0.43
Tier 4 Participant adds Customer liquidity of 75,000 or more contracts per day in a month	0.44

[3] The Penny Pilot was established in March 2008 and in October 2009 was expanded and extended through June 30, 2012. *See* Securities Exchange Act Release Nos. 57579 (March 28, 2008), 73 FR 18587 (April 4, 2008) (SR–NASDAQ–2008–026) (notice of filing and immediate effectiveness establishing Penny Pilot); 60874 (October 23, 2009), 74 FR 56682 (November 2, 2009) (SR–NASDAQ–2009–091) (notice of filing and immediate effectiveness expanding and extending Penny Pilot); 60965 (November 9, 2009), 74 FR 59292 (November 17, 2009) (SR–NASDAQ–2009–097) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 61455 (February 1, 2010), 75 FR 6239 (February 8, 2010) (SR–NASDAQ–2010–013) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 62029 (May 4, 2010), 75 FR 25895 (May 10, 2010) (SR–NASDAQ–2010–053) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 65969 (December 15, 2011, 76 FR 79268 (December 21, 2011) (SR–NASDAQ–2011–169) (notice of filing and immediate effectiveness extension and replacement of Penny Pilot). *See also* Exchange Rule Chapter VI, Section 5.

Monthly volume	Rebate to add liquidity
Tier 5 [a] Participant adds (1) Customer liquidity of 25,000 or more contracts per day in a month, (2) the Participant has certified for the Investor Support Program set forth in Rule 7014; and (3) the Participant executed at least one order on NASDAQ's equity market	0.42

[a] For purposes of Tier 5, the Exchange will allow a NOM Participant to qualify for the rebate if a NASDAQ member under common ownership with the NOM Participant has certified for the Investor Support Program and executed at least one order on NASDAQ's equity market. Common ownership is defined as 75 percent common ownership or control.

Currently, Tier 3 firms that add 50,000 or more contracts per day in a month of Customer liquidity, in Penny Options, receive a rebate of $0.42 per contract. The Exchange is proposing to increase the Tier 3 Customer rebate from $0.42 per contract to $0.43 per contract. The Exchange also proposes to amend the number of contracts required to qualify for Tier 3 from 50,000 or more contracts per day in a month to require NOM Participants to add between 50,000 to 74,999 contracts per day in a month of Customer liquidity in Penny Options to qualify for the increased $0.43 Customer rebate.

Currently, Tier 4 firms that (1) add Customer liquidity of 100,000 or more contracts per day in a month of Customer order liquidity in Penny Options, and (2) provide 40,000 or more contracts per day of NOM Market Maker liquidity per day in a month receive a rebate of $0.43 per contract if both criteria are met. For purposes of determining qualification for this tier, the Exchange currently aggregates [4] the trading activity of separate NOM Participants in calculating the average daily volume if there is at least 75% common ownership or control between the NOM Participants. The Exchange proposes to amend the criteria to qualify for Tier 4 from 100,000 or more contracts per day in a month to 75,000 or more contracts per day in a month of Customer liquidity in Penny Options and also remove the second criteria to qualify for Tier 4. The Exchange would therefore remove the requirement that a NOM Market Maker add liquidity of 40,000 or more contracts per day in a month. In addition the Exchange proposes to increase the current Tier 4 Customer rebate of $0.43 per contract to $0.44 per contract. The Exchange would also remove note ''(a)'', which was associated with the second criteria of Tier 4, which is no longer necessary as the NOM Marker Maker requirement would no longer be a condition to receive the Tier 4 Customer rebate.

Currently, Tier 5 firms that (1) provide 25,000 or more contracts per day in a month of Customer order liquidity in Penny Options, (2) where the Participant has certified for the Investor Support Program (''ISP'') as set forth in Rule 7014 [5]; and (3) where the Participant executed at least one order on NASDAQ's equity market receive a $0.41 per contract Customer rebate. The Exchange proposes to amend Tier 5 to increase the Customer rebate in Penny Options from $0.41 per contract to $0.42 per contract. The Exchange would also renumber the current note ''(b)'' as note ''(a).'' The Exchange is not proposing any changes to current Tiers 1 and 2.[6]

The Exchange also proposes to subsidize the proposed increased Customer Rebates to Add Liquidity in Penny Options by increasing the Customer Fee for Removing Liquidity in Penny Options from $0.44 per contract to $0.45 per contract. The Exchange believes that this increase will allow the Exchange to compete more effectively by subsidizing rebates offered on Customer orders.

The Exchange also proposes to make minor amendments to Section 2 including amending the title of Section 2 from ''NASDAQ Options Market –Fees'' to ''NASDAQ Options Market –Fees and Rebates.'' to more specifically describe the Rule. The Exchange also proposes to correct a cross-reference to the NASDAQ OMX PHLX LLC (''Phlx'') ''Fee Schedule.'' The Exchange proposes to update the title of the ''Fee Schedule'' to the ''Pricing Schedule'' in accordance with a recent amendment filed by Phlx.[7]

2. Statutory Basis

NASDAQ believes that the proposed rule changes are consistent with the provisions of Section 6 of the Act,[8] in general, and with Section 6(b)(4) of the Act,[9] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which NASDAQ operates or controls.

The Exchange believes that the proposed new pricing tiers are reasonable, equitable and not unfairly discriminatory because they continue an existing program [10] to encourage broker-dealers acting as agent for Customer orders to select the Exchange as a venue to post Customer orders. The Exchange believes that its success at attracting Customer order flow benefits all market participants by improving the quality of order interaction and executions at the Exchange. The Exchange believes the existing monthly volume thresholds have incentivized firms that route Customer orders to the Exchange to increase Customer order flow to the Exchange. The Exchange desires to continue to encourage firms that route Customer orders to increase Customer order flow to the Exchange by offering greater Customer rebates for greater liquidity added to the Exchange.

Specifically, the Exchange believes that the increased Customer rebates in Penny Options would further incentivize firms to continue to send more Customer volume to the Exchange. By increasing the Customer rebates in Tiers 3, 4 and 5 by $0.01 per contract each, the Exchange would further encourage NOM Participants to transact a greater number of Customer rebates in Penny Options. With respect to Tier 3, NOM Participants that qualify for these Customer rebates today should qualify

[4] Aggregation is necessary and appropriate because certain NOM participants conduct Customer and NOM Market Maker trading activity through separate but related broker-dealers.

[5] For a detailed description of the ISP, see Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness) (the ''ISP Filing''). See also Securities Exchange Act Release Nos. 63414 (December 2, 2010), 75 FR 76505 (December 8, 2010) (NASDAQ–2010–153) (notice of filing and immediate effectiveness); and 63628 (January 3, 2011), 76 FR 1201 (January 7, 2011) (NASDAQ–2010–154) (notice of filing and immediate effectiveness).

[6] The Exchange currently pays an additional rebate of $0.01 per contract for each Customer order of 5,000 or more, displayed or non-displayed contracts, which adds liquidity in Penny Options as long as the NOM Participant qualified for a rebate in Tier 2, 3, 4 or 5 for that month. This is not being amended in this proposal.

[7] *See* SR–Phlx–2012–35.

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

[10] The Exchange adopted these monthly volume achievement tiers in September 2011. *See* Securities Exchange Act Release Nos. 65317 (September 12, 2011), 76 FR 57778 (September 16, 2011) (SR–NASDAQ–2011–124), 65317 (September 12, 2011), 76 FR 61129 (October 3, 2011) (SR–NASDAQ–2011–127), 66126 (January 10, 2012), 77 FR 2335 (January 17, 2012) (SR–NASDAQ–2012–003) and 66360 (February 8, 2012), 77 FR 8312 (February 14, 2012) (SR–NASDAQ–2012–022).

for the increased rebate which continues to require at least 50,000 contracts per day in a month of Customer liquidity, but also amends the criteria to between 50,000 and 74,999 contracts of Customer liquidity in Penny Options to qualify for the increased rebate of $0.43 per contract. NOM Participants who currently transact greater than 74,999 contracts per day in a month today would be entitled to an even greater rebate because they would qualify for the increased Tier 4 rebate of $0.44 per contract. The Exchange is amending Tier 4 to lower the first criteria from 100,000 or more contracts of Customer liquidity to 75,000 or more contracts of Customer liquidity in Penny Options and remove the second criteria to qualify for the Customer rebate.[11] Therefore NOM Participants would only be required to add 75,000 or more contracts per day in a month of Customer liquidity in Penny Options to receive the increased Customer rebate of $0.44 per contract. The lower criteria in Tier 4 would allow NOM Participants that currently qualify for Tier 3, because they add greater than 75,000 contracts per day in a month of Customer liquidity in Penny Options, to qualify for the $0.44 per contract rebate and also encourage other NOM Participants to add more Customer liquidity to qualify for an even greater rebate than that offered for Tier 3.

The Exchange's proposal to increase the rebates in Tiers 3, 4 and 5 and amend the Tier 3 and 4 criteria as described herein is reasonable because it should further encourage NOM Participants to qualify for Customer rebates in Penny Options by transacting a greater number of Customer contracts in Penny Options and increase liquidity on NOM. Increased liquidity benefits all market participants on the Exchange. In addition, the increased Tier 5 Customer rebate should further encourage increased activity in both the NASDAQ Options Market and in the ISP of the NASDAQ equity market. The Exchange's proposal to increase the rebates in Tiers 3, 4 and 5 as well as amend the criteria for Tiers 3 and 4 is equitable and not unfairly discriminatory because all NOM Participants that transact Customer orders in Penny Options are eligible for the Customer rebates.[12] In addition, the proposals to amend the Tier 3 criteria to between 50,000 and 74,999 contracts of Customer liquidity in Penny Options and lower the Tier 4 criteria to 75,000 or more contracts of Customer liquidity in Penny Options and eliminate the second criteria are equitable and not unfairly discriminatory because they should encourage NOM Participants that currently qualify for Tier 3 today to obtain the increased Tier 4 rebate and encourage other NOM Participants to transact additional Customer orders in Penny Options to obtain the increased rebates.

The Exchange's proposal to increase the Customer Fee for Removing Liquidity in Penny Options is reasonable because the Exchange is seeking to recoup costs associated with offering Customer rebates in Penny Options to attract greater liquidity to the Exchange. The increased liquidity benefits all market participants. The Exchange's proposal to increase the Customer Fee for Removing Liquidity in Penny Options is equitable and not unfairly discriminatory because all market participants would uniformly be assessed a $0.45 per contract Customer Fee for Removing Liquidity in Penny Options. Currently, Professionals, Firms, Non-NOM Market Makers and NOM Market Makers are assessed a $0.45 per contract Fee for Removing Liquidity in Penny Options. The Exchange believes that increasing the Customer Fee for Removing Liquidity by $0.01 per contract ($0.44 per contract to $0.45 per contract) allows the Exchange to recoup costs and offer even greater Customer rebates, thereby benefitting all market participants by attracting Customer order flow to NOM.

The Exchange's proposals to amend the title of Section 2 to reflect the rebates offered and also update a cross-reference to the Phlx fees are reasonable, equitable and not unfairly discriminatory because these amendments provide greater clarity and accuracy to the Rule text.

The Exchange operates in a highly competitive market comprised of nine U.S. options exchanges in which sophisticated and knowledgeable market participants can and do send order flow to competing exchanges if they deem fee levels at a particular exchange to be excessive or rebate opportunities to be inadequate. The Exchange believes that the proposed fee and rebate scheme are competitive and similar to other fees, rebates and tier opportunities in place on other exchanges. The Exchange believes that this competitive marketplace materially impacts the fees and rebates present on the Exchange today and substantially influences the proposal set forth above.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2012–048 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–048. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's

[11] As previously mentioned, the Exchange would no longer require 40,000 or more contracts per day in a month of NOM Market Maker liquidity.

[12] Tier 1 pays a rebate for NOM Participants that add Customer liquidity of up to 14,999 contracts per day in a month of Penny Options. There is no required minimum volume of Customer orders to qualify for a Customer Rebate to Add Liquidity.

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2012–048 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8838 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66766; File No. SR–ICC–2012–05]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change to Membership Qualifications

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder[2] notice is hereby given that on April 3, 2012, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of Terms of Substance of the Proposed Rule Change

The purpose of proposed rule change is to conform the ICC membership qualifications to be in compliance with Commodity Futures Trading Commission (''CFTC'') Regulations 39.12(a)(2)(ii) and 39.12(a)(2)(iii) no later than the May 7, 2012 effective date of CFTC Regulations 39.12(a)(2)(ii) and 39.12(a)(2)(iii). ICC believes these changes are also consistent with Commission Proposed Rule 17Ad–22(b)(7).

As discussed in more detail in Item II(A) below, the changes to Chapters 1 and 2 of the ICC Rules provide for amendments to the membership qualifications of ICC and related definitions.

II. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

A. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

CFTC Regulation 39.12(a)(2)(ii) provides that ''the participant requirements shall set forth capital requirements that are based on objective, transparent, and commonly accepted standards that appropriately match capital to risk. Capital requirements shall be scalable to the risks posed by clearing members.''

Accordingly, ICC revised Rule 209 (Risk-Based Capital Requirement) to provide that if at any time and for so long as a Clearing Participant has a required contribution to the ICC General Guaranty Fund that exceeds 25% of its ''excess net capital,'' ICC may (in addition to imposing the trading activity limitations provided for in ICC Rule 203(b)) require such Clearing Participant to prepay and maintain with ICE Clear Credit an amount up to the Clearing Participant's assessment obligation. ICC Rule 102, the definitional section of the Rules, has been amended to define ''excess net capital'' as the amount reported on Form 1–FR–FCM or FOCUS Report or as otherwise reported to the CFTC under CFTC Rule 1.12. For a Participant that is not an FCM or a Broker-Dealer, there is no standard equivalent to ''excess net capital'' which can be utilized across all types of Clearing Participant entities. Therefore, Rule 102 places the burden on the Clearing Participant to demonstrate that its capital exceeds the capital requirement that would be applicable to it if it were an FCM, as determined pursuant to a methodology acceptable to ICC.

CFTC Regulation 39.12(a)(2)(iii) provides that ''a derivatives clearing organization *shall not set a minimum capital requirement of more than $50 million* for *any person* that seeks to become a clearing member in order to clear swaps''. [Emphasis added.]

Accordingly, ICC revised Rule 201(b)(ii) incorporates the CFTC mandated $50,000,000 minimum adjusted net capital requirement for all ICC Clearing Participants. For a Participant that is not an FCM or a Broker-Dealer, there is no standard equivalent to ''adjusted net capital'' which can be utilized across all types of Clearing Participant entities. Therefore, Rule 201(b)(ii)(C) places the burden on the Clearing Participant to demonstrate that its capital exceeds the capital requirement that would be applicable to it if it were an FCM, as determined pursuant to a methodology acceptable to ICC.

In addition, in order to promote compliance with the capital adequacy requirements, Rule 201(b)(i) has been amended to provide that a Clearing Participant must be regulated for capital adequacy by a competent authority such as the CFTC, SEC, Federal Reserve Board, Office of the Comptroller of the Currency, U.K. Financial Services Authority or any other regulatory body ICC designates from time to time for this purpose, or is an affiliate of an entity that satisfies the capital adequacy regulatory requirement and is subject to consolidated holding company group supervision.

The Board of Managers approved the above amendments on March 22, 2012 after receiving recommendations to approve from the ICE Clear Credit Risk Committee on March 21, 2012, and the ICE Clear Credit Risk Management Subcommittee on March 7, 2012. However, the ICE Clear Credit Board, Risk Committee and Risk Management Subcommittee expressed concern with respect the Amended Rules relating to Commission Proposed Rule 17Ad–22(b)(7) and CFTC Regulation 39.12(a)(2)(iii) and only recommended approval or approved the same in order

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

for ICC to be in compliance with the law. The ICE Clear Credit Board, Risk Committee and Risk Management Subcommittee discussed with concern the extreme reduction in the minimum capital requirement from the current ICC requirement of $5,000,000,000 for non-FCM or Broker Dealer Clearing Participants to the minimum capital requirement of $50,000,000 mandated by CFTC Regulation 39.12(a)(2)(iii) and proposed in Commission Rule 17Ad–22(b)(7).

Similarly, the ICE Clear Credit Board, Risk Committee and Risk Management Subcommittee discussed the very significant reduction in the minimum capital requirement initially established by ICC for its FCM or Broker Dealer Clearing Participants of $500,000,000 (subsequently reduced to $100,000,000) to the minimum capital requirement of $50,000,000 mandated by CFTC Regulation 39.12(a)(2)(iii) and proposed in Commission Rule 17Ad–22(b)(7). The concerns raised by the ICE Clear Credit Board, Risk Committee, and Risk Management Subcommittee are mitigated in part by the Risk-Based Capital Requirement ICC is proposing.

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act and the rules and regulations thereunder applicable to it. ICC believes that the proposed membership requirements will comply with the Act and the rules and regulations thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

ICC does not believe that the proposed rule change would impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

- Electronic comments may be submitted by using the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*), or send an email to *rule-comments@sec.gov.* Please include File No. SR–ICC–2012–05 on the subject line.
- Paper comments should be sent in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICC–2012–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's Web site at *https://www.theice.com/publicdocs/regulatory_filings/032812_SEC_ICEClearCredit.pdf.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–ICC–2012–05 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[3]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8790 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66764; File No. SR–EDGA–2012–14]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to New EDGA Rule 11.22 Requiring Members To Input Accurate Information Into the System

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 2, 2012, EDGA Exchange, Inc. (the "Exchange" or "EDGA") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt new EDGA Rule 11.22 to require Members to input accurate information into the System,[3] including, but not limited to, identifying each order accurately as a principal, agency, or riskless principal order. The text of the proposed rule change is available on the Exchange's Web site at *www.directedge.com,* at the Exchange's principal office, and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these

---

[3] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term "System" is defined in EDGA Rule 1.5(cc).

statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add new EDGA Rule 11.22 for the purpose of increasing transparency and to enhance the surveillance database and audit trail of transaction data used by the Exchange in surveillance of its market. The proposed rule change would require Members to input accurate information into the System, including, but not limited to, identifying the capacity of each order accurately as a principal, agency, or riskless principal order. For purposes of surveillance, the Exchange currently identifies the capacity of each order as principal, agency, or riskless principal; however, several other capacities are accepted upon order entry, including no response, which are thereafter mapped to one of the above-listed order capacities. By requiring Members to accurately submit an order capacity for each order and to otherwise input accurate information into the System, the Exchange will be able to more precisely identify the type of order received and more effectively surveil for abusive trading.

EDGA does not currently have a rule that makes an explicit statement regarding a Member's obligation to input accurate information into the System. However, currently, in FIX tag 47,[4] Members are asked to populate their capacity when entering orders into the Exchange's System; however, if the field is left blank by the Member, it is automatically populated with an ''A'' value (denoting agency).

Notwithstanding, EDGA believes that disciplinary cases against Members entering inaccurate or incomplete information may be brought appropriately under EDGA Rule 3.1, which requires Members to observe high standards of commercial honor and just and equitable principles of trade. Rule 3.1 protects the investing public and the securities industry from dishonest practices that are unfair to investors or hinder the functioning of a free and open market, even though those practices may not be illegal or violate a specific rule or regulation. Because of the regulatory importance of inputting accurate information into the System, EDGA believes a rule that directly addresses Members' obligation to provide accurate information is warranted. The proposed rule makes clear Members' obligation to input accurate information into the System and that failure to do so would be considered a violation of EDGA Rules. In addition, once the rule is effective, if Members do not input the capacity in which they are acting (principal, agent, or riskless principal) into the System, the order will be rejected back to the Member by the Exchange.

EDGA notes that both BATS Exchange Inc. (''BATS'') and BATS–Y Exchange, Inc. (''BYX'') have adopted rules materially identical to proposed EDGA Rule 11.22.[5] Similarly, the Commission has previously approved rules proposed by the NASDAQ Stock Market LLC (''NASDAQ'') requiring participants to ensure that accurate information is entered into NASDAQ's system, including, but not limited to, the capacity in which the participant is acting.[6] Thus, the proposed rule change would bring EDGA Rules in line with those of other self-regulatory organizations.

In order to allow Members sufficient time to review and complete any systems changes necessitated by this filing, the Exchange will notify Members via information circular of an exact implementation date for the proposed rule change, which will be no later than August 31, 2012.

2. Statutory Basis

The rule change proposed in this submission is consistent with the requirements of Section 19(b)(1) of the Act[7] and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[8] Specifically, for the reasons described above, the proposed change is consistent with Section 6(b)(5) of the Act,[9] because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest. Specifically, the changes proposed herein will serve to promote the accuracy of information input into the Exchange. Accurate information is necessary for the efficient and fair operation of the Exchange, and will assist the Exchange in surveilling the markets for abusive or otherwise violative trading activity.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) of the Act[10] and paragraph (f)(6) of Rule 19b–4 thereunder.[11] The Exchange asserts that the proposed rule change: (1) Will not significantly affect the protection of investors or the public interest, (2) will not impose any significant burden on competition, and (3) will not become operative for 30 days from the date on which it was filed, or such shorter time as designated by the Commission. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing, or such shorter time as the Commission may designate.[12] In addition, the Exchange believes that the proposal to require Members to identify the capacity of each order as either a principal, agency, or riskless principal order does not present any policy issues that have not previously been considered by the

[4] Members utilize an industry standard Financial Information eXchange (''FIX'') protocol to electronically enter orders into the System. Members populate certain FIX fields (*i.e.,* tags) to indicate certain terms of the order. FIX tag 47 is used to identify the Member's capacity.

[5] *See* Securities Exchange Act Release No. 63969 (February 25, 2011), 76 FR 12155 (March 4, 2011); and Securities Exchange Act Release No. 63970 (February 25, 2011), 76 FR 12204 (March 4, 2011).

[6] *See* Securities Exchange Act Release No. 59547 (March 10, 2009), 74 FR 11386 (March 17, 2009).

[7] 15 U.S.C. 78s(b)(1).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

Commission, but rather, is a minor change to the Exchange's existing rules that is consistent with the rules of other national securities exchanges.[13] For the foregoing reasons, this rule filing qualifies for immediate effectiveness as a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–EDGA–2012–14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2012–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2012–14 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8788 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[13] *See, e.g.,* NASDAQ Rule 4611(a)(6), BATS Rule 11.21 and BYX Rule 11.21.

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66760; File No. SR–C2–2012–004]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Order Approving a Proposed Rule Change Relating To Stock-Option Orders

April 6, 2012.

I. Introduction

On February 7, 2012, the C2 Options Exchange, Incorporated (''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend C2 Rule 6.13, ''Complex Order Execution,'' to, among other things, revise C2's procedures for electronically executing stock-option orders. The proposed rule change was published for comment in the **Federal Register** on February 21, 2012.[3] The Commission received no comment letters regarding the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposal

C2 proposes to amend C2 Rule 6.13 to adopt definitions of complex order and stock-option order, and to provide procedures for electronically executing stock-option orders.

A. Definitions of Complex Order and Stock-Option Order

C2 proposes to amend C2 Rule 6.13(a) to include definitions of complex order[4] and stock-option order.[5] C2 notes that its new definitions of complex order and stock-option order are consistent with those of another options exchange,[6] and with the definitions used in C2 Chapter VI, Section E, ''Intermarket Linkage,'' which incorporates by reference Chicago Board Options Exchange, Inc. (''CBOE'') CBOE Rule 6.80(4).

C2 Rule 6.13(b)(2) currently permits only complex orders with no more than four legs to be placed in the Complex Order Book (''COB''). C2 proposes to remove this limitation and to provide that only complex orders and stock-option orders with no more than the applicable number of legs, as determined by C2 on a class-by-class basis, will be eligible for processing.[7]

B. Execution of Stock-Option Orders

1. Legging

C2 proposes to add Interpretation and Policy .06 to Rule 6.13 to provide that stock-option orders will execute against other stock-option orders through COB and the Complex Order RFR Auction (''COA''). Stock-option orders will not be legged against the individual component legs, except in one limited circumstance, as described below.[8] C2 believes that the proposal will provide for more efficient execution and processing of stock-option orders and will help to mitigate the potential risks associated with legging stock-option orders, including the risk of an

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 66393 (February 14, 2012), 77 FR 10020 (''Notice'').

[4] C2 proposes to define a complex order as any order involving the execution of two or more different options series in the same underlying security occurring at or near the same time in a ratio that is equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) (or such lower ratio as may be determined by the Exchange on a class-by-class basis) and for the purpose of executing a particular investment strategy. *See* C2 Rule 6.13(a)(1).

[5] C2 proposes to define a ''stock-option order'' as an order to buy or sell a stated number of units of an underlying stock or a security convertible into the underlying stock (''convertible security'') coupled with the purchase or sale of options contract(s) on the opposite side of the market representing either (i) the same number of units of the underlying stock or convertible security; or (ii) the number of units of the underlying stock necessary to create a delta neutral position, but in no case in a ratio greater than eight (8) options contracts per unit of trading of the underlying stock or convertible security established for that series by The Options Clearing Corporation (or such lower ratio as may be determined by the Exchange on a class-by-class basis). *See* C2 Rule 6.13(a)(2).

[6] *See* ISE Rule 722(a)(1) and (2).

[7] *See* C2 Rule 6.13(a)(1) and (2).

[8] *See* C2 Rule 6.13, Interpretation and Policy .06(d).

unhedged position if one leg of the order cannot be executed.[9]

C2 proposes to permit legging for an eligible market stock-option order that cannot be executed in full, or in a permissible ratio, at the conclusion of a COA.[10] At the conclusion of a COA, any remaining balance of the option leg(s) of an eligible market stock-option order will route to C2's system for processing as a simple market order(s), and C2 will electronically transmit any remaining balance of the stock leg to a designated broker-dealer (as described below) for processing as a market order.[11] The designated broker-dealer will represent the stock leg on behalf of the party that submitted the stock-option order.

For purposes of this legging functionality, an eligible market order is a stock-option order that is within certain parameters determined by C2 and for which the NBBO is within designated size and price parameters, as determined by C2 for the individual leg.[12] The designated NBBO price parameters will be determined based on a minimum bid price for sell orders.[13] The Exchange may also determine on a class-by-class basis to limit the trading times within regular trading hours that the legging functionality will be available.[14]

C2 believes that the order eligibility parameters for eligible market stock-option orders will help to mitigate the potential risks associated with legging stock-option orders, including the risk of an order drilling through multiple price points on another exchange (thereby resulting in executions at prices that are far from the NBBO and potentially erroneous), and the risk that one leg of the stock-option order will go unexecuted (resulting in an incomplete execution and a partial position that is unhedged).[15]

2. Communication of Stock Leg to a Designated Broker-Dealer(s)

Under the proposal, C2 will electronically communicate the stock leg of a stock-option order to a designated broker-dealer(s) for execution on behalf of a Permit Holder.[16] C2 believes that this procedure will provide a more efficient means for processing stock-option orders.[17] To participate in stock-option order automated processing, a Permit Holder must enter into a brokerage agreement with one or more designated broker-dealers that are not affiliated with C2.[18]

C2 will transmit the stock component of a stock-option order to a designated broker-dealer as two paired orders with a designated limit price (except in the limited circumstance described above for eligible market stock-option orders) after the Exchange's trading system determines that a stock-option order trade is possible and at what net prices.[19] The designated broker-dealer will act as agent for the stock leg of a stock-option order and will be responsible for the proper execution, trade reporting, and submission to clearing of the stock trade.[20] After C2 communicates the stock orders to the designated broker-dealer for execution, the designated broker-dealer will be responsible for determining whether the orders may be executed in accordance with all of the rules applicable to execution of equity orders, including compliance with applicable short sale, trade-through, and trade reporting rules.[21] If the designated broker-dealer cannot execute the stock leg at the designated price, the stock-option order will not be executed on the Exchange.[22]

A Permit Holder may submit a stock-option order only if the order complies with the qualified contingent trade exemption (''QCT Exemption'') from Rule 611(a) of Regulation NMS,[23] and a Permit Holder submitting a stock-option order represents that the order complies with the QCT Exemption.[24] In addition, as described more fully in the Notice, C2's system will validate compliance with the QCT Exemption with respect to each matched order communicated to the designated broker-dealer.[25]

C2 intends to file a separate proposal to establish fees related to the routing of the stock portion of a stock-option order.[26]

C. Allocation Algorithms and Priority

1. COB and COA Allocation Algorithms

Stock-option orders in COB and COA will execute according to an electronic allocation algorithm. Specifically, stock-option orders in COB that are marketable against each other will execute automatically.[27] Multiple stock-option orders at the same price will be allocated pursuant to the rules of trading priority otherwise applicable to incoming electronic orders in the individual component legs,[28] or pursuant to another allocation algorithm designated by C2 under C2 Rule 6.13, Interpretation and Policy .05.[29]

Stock-option orders executed against other stock-option orders through a COA will trade first at the best net price(s) and, at the same price, in the sequence set forth in C2 Rule 6.13(c)(5)(B)–(D).[30]

2. Priority

For a stock-option order to execute against another stock-option order in COB or COA, the execution must occur at a price where the option leg(s) of the stock-option order have priority over the

[9] *See* Notice, 77 FR at 10021–22.

[10] *See* C2 Rule 6.13, Interpretation and Policy .06(d). For purposes of the legging functionality, an eligible market order is a stock-option order that is within the designated size and order type parameters, as determined by C2 on a class-by-class basis, and for which the national best bid or offer (''NBBO'') is within designated size and price parameters, as determined by C2 for the individual leg. *See* C2 Rule 6.13, Interpretation and Policy .06(d).

[11] *See* C2 Rule 6.13, Interpretation and Policy .06(d).

[12] *See id.*

[13] *See id.*

[14] *See id.*

[15] *See* Notice, 77 FR at 10022.

[16] *See* C2 Rule 6.13, Interpretation and Policy .06(a).

[17] *See* Notice, 77 FR at 10021.

[18] *See* C2 Rule 6.13, Interpretation and Policy .06(a).

[19] *See* Notice, 77 FR at 10020.

[20] *See id.* at 10020–21.

[21] *See id.* at 10021.

[22] *See id.* at 10021 and C2 Rule 6.13, Interpretation and Policy .06.

[23] *See* 17 CFR 242.611(a). *See also* Securities Exchange Act Release No. 57620 (April 4, 2008), 73 FR 19271 (April 9, 2008) (order modifying the QCT Exemption) and Securities Exchange Act Release No. 53489 (August 31, 2006), 71 FR 52829 (September 7, 2006) (order establishing the QCT Exemption).

[24] *See* C2 Rule 6.13, Interpretation and Policy .06(a).

[25] *See* Notice, 77 FR at 10021.

[26] *See id.* at 10021.

[27] *See* C2 Rule 6.13, Interpretation and Policy .06(c).

[28] *See id.* C2 notes that the allocation algorithms for the individual series legs include price-time, pro-rata, and price-time with primary public customer and secondary trade participation right priority and an optional priority overlay pertaining to market turner priority. *See* Notice, 77 FR at footnote 15. *See also* C2 Rule 6.12.

[29] *See* C2 Rule 6.13, Interpretation and Policy .06(c). C2 Rule 6.13, Interpretation and Policy .05 allows C2 to determine, on a class-by-class basis, which electronic matching algorithm from Rule 6.12 will apply to executions in COB in lieu of the algorithm specified in C2 Rule 6.13(b)(1)(B).

[30] *See* C2 Rule 6.13, Interpretation and Policy .06(d). Under Interpretation and Policy .06(d), a stock-option order that was subject to a COA would execute against other stock-option orders first at the same net price(s) and, at the same price, in the following sequence: (i) Against public customer stock-option orders resting in COB before, or that are received during, the COA Response Time Interval, and public customer RFR responses, with multiple orders ranked by time priority; (ii) against non-public customer stock-option orders resting in the COB before the COA Response Time Interval, with multiple orders subject to the rules of trading priority otherwise applicable to incoming orders in the individual component legs; and (iii) against non-public customer stock-option orders resting in the COB that are received during the COA Response Time Interval and non-public customer responses, with multiple orders subject to the rules of trading priority otherwise applicable to incoming orders in the individual component legs.

individual orders and quotes in C2's Book.[31] To satisfy this condition, the individual option leg(s) of the stock-option order: (i) Must not trade at a price that is inferior to C2's best bid (offer) in the individual component series; and (ii) must not trade at C2's best bid (offer) in the individual component series if one or more public customer orders are resting at the best bid (offer) price in each of the component option series and the stock-option order could otherwise be executed in full or in a permissible ratio.[32] The option leg(s) of a stock-option order may be executed in a one-cent increment regardless of the minimum quoting increment applicable to that series.[33]

D. Provisions Applicable to Marketable Stock-Option Orders

Several provisions in the proposal address the handling of a stock-option order that is or becomes marketable. First, to the extent that a marketable stock-option order cannot be executed in full, or in a permissible ratio, when it is routed to COB or following a COA, any part of the order that can execute will execute and the part that cannot automatically execute will be cancelled.[34]

Second, to the extent that a stock-option order resting in COB becomes marketable against the derived net market, the full order will be subject to a COA.[35] The derived net market for a strategy will be calculated using C2's best bid or offer in the individual option series leg(s) and the NBBO in the stock leg.[36] After being subject to a COA, any part of the order that may be executed will be executed automatically and the part that cannot execute automatically will be canceled.[37] C2 believes that automatically initiating a COA after a resting stock-option order becomes marketable against the derived net market will provide an opportunity for market participants to match or improve the net price and provide an opportunity for automatic execution of the order.[38] C2 notes that this system feature will not be applicable to a resting stock-option order that becomes marketable against another stock-option order(s).[39]

E. Price Check Parameters

C2 proposes to adopt a new price check parameter applicable to the electronic processing of stock-option orders.[40] This new price check parameter will allow C2 to determine, on a class-by-class basis, and announce via Regulatory Circular, not to automatically execute a stock-option order if, following a COA, the execution would not be within the acceptable derived net market for the strategy that existed at the start of the COA.[41] A stock-option order that is not within the acceptable derived net market will be cancelled.[42]

The ''acceptable derived net market'' for a strategy will be calculated using C2's best bid or offer in the individual option series leg(s) and the NBBO in the stock leg plus/minus an acceptable tick distance.[43] C2 will determine the ''acceptable tick distance'' on a class-by-class basis.[44] C2 believes it is reasonable and appropriate to use the Exchange's best bid and offer for the individual series to calculate the acceptable derived net market for the option series leg(s) because the option component leg(s) of a stock-option order are not permitted to trade at a price that is inferior to the Exchange's best bid and offer.[45] C2 believes it is reasonable and appropriate to use the NBBO plus/minus an acceptable tick distance to calculate the acceptable derived net market for the stock component because C2 believes the NBBO should serve as a reasonable proxy for what may be considered a reasonable price for the automatic execution of the stock component leg.[46] C2 believes, further, that it also may be appropriate to consider some range outside the NBBO in determining the acceptable tick distance because the stock leg of a stock-option order that qualifies for the QCT Exemption [47] may be executed outside the NBBO for the stock.[48] Accordingly, in establishing the acceptable tick distance for the stock leg of the order, C2 would have the flexibility to use the NBBO (which would equate to an acceptable tick distance of 0) or a range outside the NBBO.[49]

In classes where this price check parameter is available, it will also be available for COA responses under C2 Rule 6.13(c); Automated Improvement Mechanism (''AIM'') and Solicitation Auction Mechanism stock-option orders and responses under C2 Rules 6.51 and 6.52; and AIM customer-to-customer immediate cross stock-option orders under C2 Rule 6.51, Interpretation and Policy .08.[50] Under these provisions, paired stock-option orders and responses will not be accepted, except that, to the extent only a paired contra-side order subject to an auction under C2 Rule 6.51 or C2 Rule 6.52 exceeds the price check parameter, the contra-side order will not be accepted and the paired original Agency Order will not be accepted or, at the order entry firm's discretion, continue processing as an unpaired stock-option order (*e.g.,* the Agency Order would route to COB or COA for processing).[51] To the extent that a contra-side order or response is marketable, its price will be capped at the price inside the acceptable derived net market.[52]

C2 also proposes to apply the existing individual series leg width price check parameter in C2 Rule 6.13, Interpretation and Policy .04(a) to market and marketable limit stock-option orders.[53] Under this price check parameter, a market or marketable limit stock-option order in a class where the price check parameter is available will not be executed automatically if the width between C2's best bid and best offer in any individual series leg is not within an acceptable price range.[54]

In addition, C2 proposes to apply the existing buy-buy (sell-sell) strategy price check parameter in C2 Rule 6.13, Interpretation and Policy .04(d) to stock-option orders.[55] Under this price check parameter, C2's system will not automatically execute a limit order where (1) all the components of the

[31] *See* Notice, 77 FR at 10022.

[32] *See* C2 Rule 6.13, Interpretation and Policy .06(b). *See also* Notice, 77 FR at 10022.

[33] *See* C2 Rule 6.13, Interpretation and Policy .06(b).

[34] *See* C2 Rule 6.13, Interpretation and Policy .06(b)(1).

[35] *See* C2 Rule 6.13, Interpretation and Policy .06(b)(2). The order would not execute automatically against the derived net market because stock-option orders will not execute against the individual legs of the order, except in the limited circumstance described above.

[36] *See id.*

[37] *See* C2 Rule 6.13, Interpretation and Policy .06(b)(1). For examples of this proposed functionality, see the Notice, 77 FR at 10023.

[38] *See* Notice, 77 FR at 10022–23.

[39] *See id.* at 10022.

[40] *See* C2 Rule 6.13, Interpretation and Policy .04(f).

[41] *See id.*

[42] *See* C2 Rule 6.13, Interpretation and Policy .04(f)(2).

[43] *See* C2 Rule 6.13, Interpretation and Policy .04(f)(1).

[44] *See id.* For an example of how this price check parameter would operate, see the Notice, 77 FR at 10023.

[45] *See* Notice, 77 FR at footnote 19.

[46] *See id.*

[47] *See supra* note 23.

[48] *See* Notice, 77 FR at footnote 19.

[49] *See id.*

[50] *See* C2 Rule 6.13, Interpretation and Policy .04(f).

[51] *See id.*

[52] *See id.* For an example of how this price check parameter would operate, see the Notice, 77 FR at 10024.

[53] *See* C2 Rule 6.13, Interpretation and Policy .04(a)(5) and Notice, 77 FR at 10024.

[54] *See* C2 Rule 6.13, Interpretation and Policy .04(a).

[55] *See* C2 Rule 6.13, Interpretation and Policy .04(d) and Notice, 77 FR at 10024.

strategy are to buy and the order is priced at zero, any net credit price, or a net debit price that is less than the number of an individual option series leg in the strategy (or applicable ratio) multiplied by the applicable minimum net price increment for the complex order; or (2) all the components of the strategy are to sell and the order is priced at zero, any net debit price, or a net credit price that is less than the number of individual option series legs in the strategy (or applicable ratio) multiplied by the applicable minimum net price increment for the complex order.[56] Instead, such a stock-option order will not be accepted.[57]

C2 believes that the price protection parameters will help to mitigate the potential risks associated with stock-option orders drilling through multiple price points and with stock-option orders being entered at net limit prices that are inconsistent with the particular ''buy-buy'' or ''sell-sell'' strategy, thereby resulting in executions that are extreme and potentially erroneous.[58]

F. Extension of the re-COA Feature to Stock-Option Orders

C2 Rule 6.13, Interpretation and Policy .02(b) provides that, for classes in which COA is activated, a non-marketable order resting at the top of the COB may be automatically subject to a COA if the order is within a number of ticks away from the current derived net market. C2 proposes to extend this ''re-COA'' feature to include stock-option orders resting at the top of the COB, and to provide that the derived net market for a stock-option order will be calculated using C2's best bid or offer in the individual option series leg(s) and the NBBO in the stock leg.[59] C2 notes that this feature would apply only to a resting non-marketable stock-option order that moves close to the derived net market, but would not apply to a resting stock-option order that becomes marketable against another stock-option order(s).[60] C2 believes that this re-COA feature will facilitate the execution of stock-option orders by providing an automated opportunity for the execution of, and price improvement to, a resting stock-option order that is priced near the current market, similar to what a Permit Holder might do if the Permit Holder were representing a stock-option order in open outcry on another exchange or entering the order into the COB.[61]

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[62] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[63] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

A. Definitions of Complex Order and Stock-Option Order

The Commission finds that the proposed definitions of complex order and stock-option order are consistent with the Act. The Commission notes that the proposed definitions of complex order and stock-option order are consistent with definitions included in the rules of another options exchange,[64] and in CBOE Rule 6.80(4), which is incorporated by reference in C2's rules.[65] In addition, the Commission believes that the proposed rule change removing the limit on the number of legs that may be included in a complex order could provide greater flexibility and permit the electronic trading on C2 of additional complex orders.

B. Execution of Stock-Option Orders

1. Legging of Stock-Option Orders

The Commission believes that the proposal to add Interpretation and Policy .06 to Rule 6.13 to provide that stock-option orders will execute against other stock-option orders through COB and COA is consistent with the Act because it could facilitate the execution of stock-option orders. The Commission notes that another options exchange similarly permits stock-option orders traded on its electronic trading platform to execute only against other stock-option orders.[66]

The Commission also believes that it is consistent with the Act for C2 to permit the legging of eligible market stock-option orders that cannot be executed in full or in a permissible ratio at the conclusion of COA because the legging functionality could provide an additional opportunity for these orders to be executed. The Commission notes that C2 believes that the eligibility parameters for eligible stock-option orders could help to mitigate the risks that may be associated with legging stock-option orders.[67]

2. Communication of Stock Leg to a Designated Broker-Dealer(s)

As described more fully above, C2 proposes to allow the Exchange to electronically communicate the stock leg of a stock-option order to a designated broker-dealer(s) for execution on behalf of a Permit Holder.[68] To participate in stock-option order automated processing, a Permit Holder must enter into a brokerage agreement with one or more designated broker-dealers that are not affiliated with C2.[69]

The designated broker-dealer will act as agent for the stock leg of a stock-option order and will be responsible for the proper execution, trade reporting, and submission to clearing of the stock trade.[70] In addition, after C2 communicates the paired stock orders to the designated broker-dealer for execution, the designated broker-dealer will be responsible for determining

[56] *See* C2 Rule 6.13, Interpretation and Policy .04(d). The minimum net price increment calculation would only apply to the individual option series legs.

[57] *See id.*

[58] *See* Notice, 77 FR at 10024.

[59] *See* C2 Rule 6.13, Interpretation and Policy .02(b).

[60] *See* Notice, 77 FR at 10024. For an example of how the re-COA feature would operate, see *id.* at 10025.

[61] *See id.* at 10024–25.

[62] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[63] 15 U.S.C. 78f(b)(5).

[64] *See* ISE Rule 722(a)(1) and (2).

[65] *See* C2 Chapter VI, Section E, ''Intermarket Linkage'' (incorporating the rules in CBOE Chapter VI, Section E). CBOE Rule 6.80(4) defines a Complex Trade for purposes of CBOE Chapter VI, Section E, ''Order Protection; Locked and Crossed Markets.'' CBOE Rule 6.81(b)(7) provides an exception from the prohibition on Trade-Throughs for any transaction that was effected as a portion of a Complex Trade.

[66] *See* Phlx Rule 1080, Commentary .08(a)(i) (stating that stock-option orders may only be executed against other stock-option orders and cannot be executed by the system against orders for the individual components).

[67] *See* Notice, 77 FR at 10022. Under C2 Rule 6.13, Interpretation and Policy .06(d), an eligible market order means a stock-option order that is within the designated size and order type parameters, determined by the Exchange on a class-by-class basis, and for which the NBBO is within designated size and price parameters, as determined by the Exchange for the individual leg. The designated NBBO price parameters will be determined based on a minimum bid price for sell orders. The Exchange may also determine on a class-by-class basis to limit the trading times within regular trading hours that the legging functionality will be available.

[68] *See* C2 Rule 6.13, Interpretation and Policy .06(a).

[69] *See id.*

[70] *See* Notice, 77 FR at 10020–21.

whether the orders may be executed in accordance with all of the rules applicable to the execution of equity orders, including compliance with applicable short sale, trade-through, and trade reporting rules.[71] A Permit Holder may submit a stock-option order only if the order complies with the QCT Exemption from Rule 611(a) of Regulation NMS, and a Permit Holder submitting a stock-option order represents that the order complies with the QCT Exemption.[72] As described more fully in the Notice, C2's system will validate compliance with the QCT Exemption with respect to each matched order communicated to the designated broker-dealer.[73]

C2's proposal to electronically communicate the stock leg of a stock-option order to a designated broker-dealer for execution is similar to rules adopted by other options exchanges.[74] Accordingly, the Commission finds that the proposal to allow C2 to electronically communicate the stock leg of a stock-option order to a designated broker-dealer that is not affiliated with C2 for execution on behalf of a Permit Holder is consistent with the Act.

C. Allocation Algorithms and Priority

1. COB and COA Allocation Algorithms

Stock-option orders in COB that are marketable against each other will execute automatically, and multiple stock-option orders at the same price will be allocated pursuant to the rules of trading priority otherwise applicable to incoming electronic orders in the individual component legs.[75] The Commission notes that this allocation provision for stock-option orders in COB is consistent with the existing complex order allocation provision in C2 Rule 6.13(b)(1)(B).[76] Accordingly, the Commission believes that the allocation provision for marketable stock-option orders in COB is consistent with the Act.

Under the proposal, stock-option orders executed against other stock-option orders through a COA will trade first at the best net price(s) and, at the same price, in the sequence set forth in C2 Rule 6.13(c)(5)(B)–(D).[77] The allocation sequence in C2 Rule 6.13(c)(5)(A)–(D) currently applies to complex orders.[78] The Commission believes that it is consistent with the Act for C2 to apply this allocation sequence, as modified to reflect that stock-option orders will not execute against individual orders and quotes in the Book, to stock-option orders as well as complex orders.

2. Priority

For a stock-option order to execute against another stock-option order in COB or COA, the execution must occur at a price where the option leg(s) of the stock-option order have priority over the individual orders and quotes in C2's Book.[79] To satisfy this condition, the individual option leg(s) of the stock-option order: (i) Must not trade at a price that is inferior to C2's best bid (offer) in the individual component series; and (ii) must not trade at C2's best bid (offer) in the individual component series if one or more public customer orders are resting at the best bid (offer) price in each of the component option series and the stock-option order could otherwise be executed in full or in a permissible ratio.[80] These provisions are consistent with the rules of other options exchanges.[81] Accordingly, the Commission believes that the priority requirements for stock-option orders in Rule 6.13, Interpretation and Policy .06(b) are consistent with the Act.

D. Provisions Applicable to Marketable Stock-Option Orders

To the extent that a marketable stock-option order cannot be executed in full or in a permissible ratio when it is routed to COB or following a COA, any part of the order that can execute will execute and the part that cannot automatically execute will be cancelled.[82] The Commission believes this provision is consistent with the Act because it describes the handling of the remaining balance of a marketable stock-option order that cannot be executed in full or in a permissible ratio.

In addition, to the extent that a stock-option order resting in COB becomes marketable against the derived net market, the full order will be subject to a COA.[83] The Commission believes that this provision is consistent with the Act.

E. Price Check Parameters

The stock-option derived net market price check parameter in C2 Rule 6.13, Interpretation and Policy .04(f) will prevent the automatic execution of a stock-option order following a COA if the execution would not be within the acceptable derived net market that existed at the start of the COA. The Commission believes that this price check parameter is consistent with the Act because it could help to prevent the automatic execution of stock-option orders at extreme or potentially erroneous prices. The Commission believes that it is reasonable to use C2's best bid and offer for the individual series legs to calculate the acceptable derived net market for the option leg(s) of a stock-option order because the option leg(s) would not be permitted to trade at a price that is inferior to CBOE's best bid or offer. The Commission believes that using the NBBO for the stock, plus or minus an acceptable tick distance, to determine the acceptable derived net market for the stock leg of a stock-option order will provide C2 with flexibility in setting this parameter. The Commission notes that a stock-option order submitted to C2's system must comply with the QCT Exemption.[84] The stock leg of a stock-option order that complies with the QCT Exemption would be permitted to trade at a price that is outside the NBBO for the stock.

[71] *See id.* at 10021.

[72] *See* C2 Rule 6.13, Interpretation and Policy .06(a).

[73] *See* Notice, 77 FR at 10021.

[74] *See* ISE Rule 722, Supplementary Material .02. *See also* Phlx Rule 1080, Commentary .08.

[75] *See id.*

[76] C2 Rule 6.13(b)(1)(B) states that the allocation of complex orders in COB will be pursuant to the rules to trading priority otherwise applicable to incoming electronic orders in the individual component legs.

[77] See C2 Rule 6.13, Interpretation and Policy .06(d). Under Interpretation and Policy .06(d), a stock-option order that was subject to a COA would execute against other stock-option orders first at the same net price(s) and, at the same price, in the following sequence: (i) Against public customer stock-option orders resting in the COB before, or that are received during, the COA Response Time Interval and public customer RFR responses, with multiple orders ranked by time priority; (ii) against non-public customer stock-option orders resting in the COB before the COA Response Time Interval, with multiple orders subject to the rules of trading priority otherwise applicable to incoming orders in the individual component legs; and (iii) against non-public customer stock-option orders resting in the COB that are received during the COA Response Time Interval and non-public customer responses, with multiple orders subject to the rules of trading priority otherwise applicable to incoming orders in the individual component legs.

[78] Because C2 will not permit the legging of stock-option orders, except with respect to eligible market stock-option orders at the conclusion of a COA, the allocation algorithm for stock-option orders will not apply C2 Rule 6.13(c)(5)(A), which provides for the execution of a complex order against individual orders and quotes in the Book. *See* C2 Rule 6.13, Interpretation and Policy .06(d).

[79] *See* Notice, 77 FR at 10022.

[80] *See* C2 Rule 6.13, Interpretation and Policy .06(b). *See also* Notice, 77 FR at 10022.

[81] *See, e.g.,* ISE Rule 722(b)(2) and NYSE Amex Rule 980NY, Commentary .03(d).

[82] *See* C2 Rule 6.13, Interpretation and Policy .06(b)(1).

[83] *See* C2 Rule 6.13, Interpretation and Policy .06(b)(2). This system feature will not be applicable to a resting stock-option order that becomes marketable against another stock-option order(s).

[84] *See* C2 Rule 6.13, Interpretation and Policy .06(a).

C2 also proposes to extend the existing individual series leg width price check parameter in C2 Rule 6.13, Interpretation and Policy .04(a) to the individual series legs of market and marketable limit stock-option orders.[85] This price check parameter prevents the automatic execution of a marketable complex order when the width between C2's best bid and offer in any individual series leg is not within an acceptable price range. C2 further proposes to extend the existing buy-buy (sell-sell) strategy price check parameter in C2 Rule 6.13, Interpretation and Policy .04(d) to stock-option orders.[86] As described more fully above, this price check parameter prevents the automatic execution of complex order at a net limit price that is inconsistent with the order's strategy (*e.g.,* an order where all of the components of a strategy are to buy, but the order is priced at 0 or at a net credit). The Commission believes it is consistent with the Act for C2 to have the ability to apply these price check parameters to stock-option orders, in addition to complex orders.

F. Extension of the re-COA Feature to Stock-Option Orders

C2 proposes to amend C2 Rule 6.13, Interpretation and Policy .02(b) to apply its ''re-COA'' feature to stock-option orders resting at the top of the COB. For classes in which COA is activated, a non-marketable stock-option order resting at the top of the COB may be automatically subject to a COA if the order is within a number of ticks away from the current derived net market.[87] The Commission believes applying the ''re-COA'' feature to stock-option orders could facilitate the execution of stock-option orders by providing an opportunity for a stock-option order resting at the top of the COB to be executed automatically. Accordingly, the Commission finds that the provision is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[88] that the proposed rule change (SR–C2–2012–004) is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[89]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8784 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

---

[85] *See* C2 Rule 6.13, Interpretation and Policy .04(a)(5) and Notice, 77 FR at 10024.

[86] *See* C2 Rule 6.13, Interpretation and Policy .04(d) and Notice, 77 FR at 10024.

[87] *See* C2 Rule 6.13, Interpretation and Policy .02(b).

[88] 15 U.S.C. 78s(b)(2).

[89] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66759; File No. SR–CBOE–2012–005]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving a Proposed Rule Change Relating to Stock-Option Orders

April 6, 2012.

I. Introduction

On February 7, 2012, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend CBOE Rule 6.53C, ''Complex Orders on the Hybrid System,'' to, among other things, revise CBOE's procedures for electronically executing stock-option orders. The proposed rule change was published for comment in the **Federal Register** on February 21, 2012.[3] The Commission received no comment letters regarding the proposed rule change. This order approves the proposed rule change.

II. Description

CBOE proposes to amend CBOE Rule 6.53C to adopt new definitions of complex order and stock-option order, and to make several changes to its procedures for electronically executing stock-option orders.

A. Definitions of Complex Order and Stock-Option Order

CBOE Rule 6.53C(a) currently defines complex orders, including stock-option orders, in terms of enumerated strategies. The proposal replaces these enumerated strategies with general definitions of complex order [4] and stock-option order.[5] According to CBOE, the investing industry creates new and legitimate investment strategies that do not necessarily fit within the current narrow definitions of complex order types, and, as a result, bona fide transactions to limit risk are not afforded the facility of execution provided to more common complex orders.[6] CBOE believes that more general definitions will provide greater flexibility in the design and use of complex strategies.[7] CBOE notes that its new definitions of complex order and stock-option order are consistent with those of another options exchange [8] and with CBOE Rule 6.80(4).

CBOE Rule 6.53C(c)(iii) currently permits only complex orders with no more than four legs to be placed in the Complex Order Book (''COB''). CBOE proposes to remove this limitation and to provide that only complex orders and stock-option orders with no more than the applicable number of legs, as determined by CBOE on a class-by-class basis, will be eligible for electronic processing.[9]

B. Execution of Stock-Option Orders

1. Legging of Stock-Option Orders

Currently, complex orders, including stock-option orders, may trade with other complex orders or by ''legging'' with the individual orders and quotes in CBOE's and CBSX's electronic books (''EBooks'') for the individual component legs, provided that the complex order can be executed in full, or in a permissible ratio, by the orders and quotes in the EBooks for the individual component legs.[10] In the case of a stock-option order that is legged, the stock component of the order would trade with CBSX's EBook and the option

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66394 (February 14, 2012), 77 FR 10026 (''Notice'').

[4] CBOE proposes to define a complex order as any order for the same account involving the execution of two or more different options series in the same underlying security occurring at or near the same time in a ratio that is equal to or greater than one-to-three (.333) and less than equal to three-to-one (3.00) (or such lower ratio as may be determined by the Exchange on a class-by-class basis) and for the purpose of executing a particular investment strategy. *See* CBOE Rule 6.53C(a)(1).

[5] CBOE proposes to define a stock-option order as any order for the same account to buy or sell a stated number of units of an underlying stock or a security convertible into the underlying stock (''convertible security'') coupled with the purchase or sale of options contract(s) on the opposite side of the market representing either (i) the same number of units of the underlying stock or convertible security; or (ii) the number of units of the underlying stock necessary to create a delta neutral position, but in no case in a ratio greater than eight (8) options contracts per unit of trading of the underlying stock or convertible security established for that series by The Options Clearing Corporation (or such lower ratio as may be determined by the Exchange on a class-by-class basis). *See* CBOE Rule 6.53C(a)(2).

[6] *See* Notice, 77 FR at 10032.

[7] *See id.*

[8] *See* ISE Rule 722(a)(1) and (2).

[9] *See* CBOE Rule 6.53C(a)(1) and (2).

[10] *See, e.g.,* CBOE Rule 6.53C, Interpretation and Policy .06(c) and (d).

series leg(s) would trade with CBOE's EBook.[11]

The proposal revises CBOE Rule 6.53C, Interpretation and Policy .06 to provide that stock-option orders will execute against other stock-option orders through COB and the Complex Order RFR Auction (''COA''), rather than by legging against individual orders and quotes.[12] CBOE believes that this change will provide for more efficient execution and processing of stock-option orders and will help to mitigate the potential risks associated with legging stock-option orders, including the risk of an unhedged position if one leg of the order cannot be executed.[13]

The proposal retains the legging functionality for an eligible market stock-option order that cannot be executed in full or in a permissible ratio at the conclusion of a COA.[14] At the conclusion of a COA, any remaining balance of the option leg(s) of an eligible market stock-option order will continue to route to the Hybrid System for processing as a simple market order(s), and CBOE will electronically transmit any remaining balance of the stock leg to a designated broker-dealer (as described below) for processing as a market order.[15] The designated broker-dealer will represent the stock leg on behalf of the party that submitted the stock-option order.

CBOE believes that the order eligibility parameters for eligible market stock-option orders help to mitigate the potential risks associated with legging stock-option orders, including the risk of an order drilling through multiple price points on another exchange (thereby resulting in executions at prices that are far from the NBBO and potentially erroneous), and the risk that one leg of the stock-option order will go unexecuted (resulting in an incomplete execution and a partial position that is unhedged).[16]

2. Eligible Market Orders

For purposes of the legging functionality, an eligible market order is a stock-option order that is within certain parameters determined by CBOE, and for which the NBBO is within designated size and price parameters, as determined by CBOE for the individual leg.[17] Currently, CBOE may determine the NBBO price parameters based on a minimum bid price for sell orders and a maximum sell price for buy orders.[18] The proposal eliminates the provision permitting CBOE to specify a designated NBBO price parameter based on a maximum offer price for buy orders because CBOE does not intend to utilize this parameter.[19]

3. Communication of Stock Leg to a Designated Broker-Dealer(s)

Under the proposal, CBOE will electronically communicate the stock leg of a stock-option order to a designated broker-dealer(s) for execution on behalf of a Trading Permit Holder, rather than routing the stock leg to CBSX.[20] CBOE believes that this procedure will provide a more efficient means for processing stock-option orders.[21] To participate in stock-option order automated processing, a Trading Permit Holder must enter into a brokerage agreement with one or more designated broker-dealers that are not affiliated with CBOE.[22] However, CBOE notes that this process is not exclusive, and that Trading Permit Holders will be able to continue using open outcry procedures to execute stock-option orders if they choose to do so.[23]

CBOE will transmit the stock component of a stock-option order to a designated broker-dealer as two paired orders with a designated limit price (except in the limited circumstance described above for eligible market stock-option orders) after the Exchange's trading system has determined that a stock-option order trade is possible and at what net prices.[24] The designated broker-dealer will act as agent for the stock leg of a stock-option order and will be responsible for the proper execution, trade reporting, and submission to clearing of the stock trade.[25] After CBOE communicates the stock orders to the designated broker-dealer for execution, the broker-dealer will be responsible for determining whether the orders may be executed in accordance will all of the rules applicable to the execution of equity orders, including compliance with the applicable short sale, trade-through, and reporting rules.[26]

A Trading Permit Holder may submit a stock-option order only if the order complies with the qualified contingent trade exemption (''QCT Exemption'') from Rule 611(a) of Regulation NMS,[27] and a Trading Permit Holder submitting a stock-option order represents that the order complies with the QCT Exemption.[28] In addition, as described more fully in the Notice, CBOE's Hybrid System will validate compliance with the QCT Exemption with respect to each matched order communicated to the designated broker-dealer.[29]

CBOE intends to file a separate proposal to establish fees related to the routing of the stock portion of a stock-option order.[30]

C. Allocation Algorithms and Priority

1. COB and COA Allocation Algorithms

Currently, stock-option orders in COB may execute against other stock-option orders or against individual orders and quotes in the EBook.[31] Because CBOE will no longer permit the legging of stock-option orders in COB against individual orders and quotes in the component legs, the proposal amends the COB algorithm to provide that stock-option orders that are marketable against each other will execute automatically.[32] Multiple stock-option orders at the same price will be allocated pursuant to the rules of trading priority otherwise applicable to incoming electronic orders in the individual component legs,[33] or

[11] *See* Notice, 77 FR at footnote 10.

[12] CBOE will retain legging functionality in one limited circumstance, as described below. *See* CBOE Rule 6.53C, Interpretation and Policy .06(d).

[13] *See* Notice, 77 FR at 10028.

[14] *See* CBOE Rule 6.53C, Interpretation and Policy .06(d). For purposes of the legging functionality, an eligible market order is a stock-option order that is within the designated size and order type parameters, as determined by CBOE on a class-by-class basis, and for which the NBBO is within designated size and price parameters, as determined by CBOE for the individual leg. *See* CBOE Rule 6.53C, Interpretation and Policy .06(d).

[15] *See* CBOE Rule 6.53C, Interpretation and Policy .06.

[16] *See* Notice, 77 FR at 10028.

[17] *See* CBOE Rule 6.53C, Interpretation and Policy .06(d).

[18] *See* CBOE Rule 6.53C, Interpretation and Policy .06(d).

[19] *See* Notice, 77 FR at footnote 16.

[20] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a). As described above, CBOE may continue to route to CBSX the stock leg of an eligible market stock-option order that cannot be executed in full or in a permissible ratio at the conclusion of a COA. *See* CBOE Rule 6.53C, Interpretation and Policy .06(d).

[21] *See* Notice, 77 FR at 10027.

[22] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a).

[23] CBOE notes that stock-option orders may be represented in open outcry by floor brokers or by CBOE PAR officials. *See* Notice, 77 FR at footnote 9. *See also* CBOE Rules 6.45A(b) and 6.45B(b).

[24] *See* Notice, 77 FR at 10026.

[25] *See* Notice, 77 FR at 10026–10027.

[26] *See* Notice, 77 FR at 10027.

[27] 17 CFR 242.611(a). *See* Securities Exchange Act Release No. 57620 (April 4, 2008), 73 FR 19271 (April 9, 2008) (order modifying the QCT Exemption). *See also* Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829 (September 7, 2006) (order establishing the QCT Exemption).

[28] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a).

[29] *See* Notice, 77 FR at 10027.

[30] *See* Notice, 77 FR at 10026–10027.

[31] *See* CBOE Rule 6.53C, Interpretation and Policy .06(b), (c), and (f).

[32] *See* CBOE Rule 6.53C, Interpretation and Policy .06(c).

[33] *See id.* CBOE notes that the allocation algorithms for the individual series legs include

pursuant to another allocation algorithm designated by CBOE under CBOE Rule 6.53C, Interpretation and Policy .09.[34]

Stock-option orders in COA, like stock-option orders in COB, currently may execute against other stock-option orders or against individual orders and quotes in the EBook.[35] Because CBOE will no longer permit the legging of stock-option orders in COA against individual orders and quotes in the component legs, except in the limited circumstance noted above, the proposal amends the COA algorithm to provide that stock-option orders executed against other stock-option orders through COA will trade first at the best net price(s) and, at the same price, in the sequence set forth in CBOE Rule 6.53C(d)(2)–(4).[36]

2. Priority

For a stock-option order to execute against another stock-option order in COB or COA, the execution must occur at a price where the option leg(s) of the stock-option order have priority over the individual orders and quotes in CBOE's EBook.[37] To satisfy this condition, the individual options legs of the stock-option order: (1) Must not trade at a price that is inferior to CBOE's best bid (offer) in the individual component series; and (2) must not trade at CBOE's best bid (offer) in the individual component series if one or more public customer orders are resting at the best bid (offer) in each of the component series and the stock-option order could otherwise be executed in full or in a permissible ratio.[38]

D. Provisions Applicable to Marketable Stock-Option Orders

Several provisions in the proposal address the handling of stock-option orders that become marketable. First, to the extent that a marketable stock-option order cannot be executed in full, or in a permissible ratio, after it is routed to COB or following a COA, any part of the order that can execute will execute and the remaining balance will be routed on a class-by-class basis to PAR or, at the order entry firm's discretion, to the order entry firm's booth.[39] If the order is not eligible to route to PAR, the remaining balance will be cancelled.[40]

Second, to the extent that a stock-option order resting in COB becomes marketable against the derived net market, the full order will be subject to a COA.[41] The derived net market will be calculated using CBOE's best bid or offer for the individual option series leg(s) and the NBBO for the stock leg.[42] CBOE believes that automatically initiating a COA after a resting stock-option order becomes marketable against the derived net market will provide an opportunity for market participants to match or improve the net price and provide an opportunity for automatic execution of the order.[43] CBOE notes that this system feature will not be applicable to a resting stock-option order that becomes marketable against another stock-option order(s).[44]

E. Price Check Parameters

CBOE proposes to adopt a new price check parameter applicable to the electronic processing of stock-option orders.[45] This price check parameter would allow CBOE to determine, on a class-by-class basis, and announce to Trading Permit Holders via Regulatory Circular, not to automatically execute a marketable stock-option order if, following a COA, the execution would not be within the acceptable derived net market for the strategy that existed at the start of the COA.[46] Such an order would route on a class-by-class basis to PAR or, at the order entry firm's discretion, to the order entry firm's booth.[47] If the order is not eligible to route to PAR, the remaining balance would be cancelled.[48]

The ''acceptable derived net market'' for a strategy will be calculated using CBOE's best bid or offer in the individual option series leg(s) and the NBBO in the stock leg plus/minus an acceptable tick distance.[49] CBOE will determine the ''acceptable tick distance'' on a class-by-class and premium basis.[50] CBOE believes that it is reasonable and appropriate to use the Exchange's best bid and offer for the individual series to calculate the acceptable derived net market for the option series leg(s) because the option component leg(s) of a stock-option order are not permitted to trade at a price that is inferior to CBOE's best bid and offer.[51] CBOE believes that it is reasonable and appropriate to use the NBBO plus/minus an acceptable tick distance to calculate the acceptable derived net market for the stock component because CBOE believes that the NBBO should serve as a reasonable proxy for what may be considered a reasonable price for the automatic execution of the stock component leg.[52] CBOE believes, further, that it also may be appropriate to consider some range outside the NBBO in determining the acceptable tick distance because the stock leg of a stock-option order that qualifies for the QCT Exemption[53] may be executed outside the NBBO for the stock.[54] Accordingly, in establishing the acceptable tick distance for the stock leg of the order, CBOE would have the flexibility to use the NBBO (which would equate to an acceptable tick

price-time, pro-rata, and the ultimate matching algorithm (''UMA'') base priorities, and a combination of various optional priority overlays pertaining to public customer priority, Market Maker participation entitlement, small order preference, and market turner. *See* Notice, 77 FR at footnote 17. *See also* CBOE Rules 6.45A and 6.45B.

[34] CBOE Rule 6.53C, Interpretation and Policy .09 allows CBOE to determine, on a class-by-class basis, which electronic matching algorithm from CBOE Rule 6.45A or 6.45B, as applicable, will apply to executions in COB in lieu of the algorithm specified in CBOE Rule 6.53C(c)(ii)(2) and (3).

[35] *See* CBOE Rule 6.53C, Interpretation and Policy .06(b), (d), and (f).

[36] *See* CBOE Rule 6.53C, Interpretation and Policy .06(d). Under Interpretation and Policy .06(d), as amended, a stock-option order that was subject to a COA would execute against other stock-option orders first, at the best net price(s) and, at the same price, in the following sequence: (i) Against public customer stock-option orders resting in COB before, or received during, the COA Response Time Interval, and public customer RFR Responses, with multiple public customer orders ranked by time priority; (ii) against non-public customer orders resting in COB before the COA Response Time Interval, with multiple orders subject to the UMA allocation in CBOE Rule 6.45A or 6.45B, as applicable; and (iii) against non-public customer orders resting in COB that are received during the COA Response Time Interval, and non-public customer RFR Responses, with multiple orders subject to the CUMA allocation in CBOE Rule 6.45A or 6.45B, as applicable.

[37] *See* Notice, 77 FR at 10028.

[38] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a) and (d). *See also* Notice, 77 FR at 10028 and 10029.

[39] *See* CBOE Rule 6.53C, Interpretation and Policy .06(b)(1). The Commission notes that CBOE intends to file a separate proposed rule change to revise CBOE Rule 6.53C, Interpretation and Policy .06 and .08 to further describe booth routing parameters and related order management terminal operations. *See* email message from Jennifer Lamie, Assistant General Counsel, Legal Division, CBOE, to Yvonne Fraticelli, Special Counsel, and Brian Baltz, Attorney, Division of Trading and Markets, Commission, dated March 27, 2012.

[40] *See id.*

[41] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a)(2). The order would not execute automatically against the derived net market because stock-option orders will no longer execute against the individual legs of the order, except in the limited circumstance described above.

[42] *See id.*

[43] *See* Notice, 77 FR at 10029.

[44] *See id.*

[45] *See* CBOE Rule 6.53C, Interpretation and Policy .08(f).

[46] *See* CBOE Rule 6.53, Interpretation and Policy .08(f)(1).

[47] *See* CBOE Rule 6.53C, Interpretation and Policy .08(f)(2). *See also* note 39, *supra.*

[48] *See id.*

[49] *See* CBOE Rule 6.53C, Interpretation and Policy .08(f)(1).

[50] *See id.*

[51] *See* Notice, 77 FR at footnote 21.

[52] *See id.*

[53] *See* note 27, *supra.*

[54] *See* Notice, 77 FR at footnote 21.

distance of 0) or a range outside the NBBO.[55]

In classes where this price check parameter is available, it will also be available for COA responses under CBOE Rule 6.53C(d), AIM and Solicitation Auction Mechanism stock-option orders and responses under CBOE Rules 6.74A and 6.74B, and customer-to-customer immediate cross stock-option orders under CBOE Rule 6.74A, Interpretation and Policy .08 (''CTC'').[56] Under these provisions, paired stock-option orders and responses will not be accepted except that, to the extent that only a paired contra-side order subject to an auction under CBOE Rule 6.74A or 6.74B exceeds the price check parameter, the contra-side order will not be accepted and the paired original Agency Order will not be accepted or, at the order entry firm's discretion, the Agency Order would continue processing as an unpaired stock option order (*e.g.,* the Agency Order would route to COB or COA for processing).[57] To the extent that a contra-side order or response is marketable, its price will be capped at the price inside the acceptable derived net market.[58]

CBOE also proposes to apply the existing individual series leg width price check parameter in CBOE Rule 6.53C, Interpretation and Policy .08(a)(i) to market and marketable limit stock-option orders.[59] Under this price check parameter, a market or marketable limit stock-option order in a class where the price check parameter was available would not be executed automatically if the width between CBOE's best bid and best offer in any individual series leg was not within an acceptable price range.[60]

CBOE believes that the price protection parameters will help to mitigate the potential risks associated with stock-option orders drilling through multiple price points, thereby resulting in executions that are extreme and potentially erroneous.[61]

F. Extension of the re-COA Feature to Stock-Option Orders

CBOE Rule 6.53C, Interpretation and Policy .04(b) provides that, for classes in which COA is activated, a non-marketable order resting at the top of the COB may be automatically subject to COA if the order is within a number of ticks away from current derived net market. The proposal extends this ''re-COA'' feature to include stock-option orders resting at the top of the COB, and to provide that the derived net market for a stock-option order will be calculated using CBOE's best bid or offer in the individual option series leg(s) and the NBBO in the stock leg.[62] CBOE notes that this feature would apply only to a resting non-marketable stock-option order that moves close to the derived net market, but would not apply to a resting stock-option order that becomes marketable against another stock-option order(s).[63] CBOE believes that this feature will facilitate the execution of stock-option orders by providing an automated opportunity for the execution of, and price improvement to, a resting stock-option order that is priced near the current market, similar to what a Trading Permit Holder might do if the Trading Permit Holder were representing the stock-option order in open outcry or entering the order into COB.[64]

G. Rule Text Reorganizations

As described more fully in the Notice, CBOE also proposes various changes to reorganize and simplify the rules governing stock-option orders by, among other things, consolidating certain provisions in CBOE Rule 6.53C, Interpretation and Policy .06.[65]

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[66] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[67] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

A. Definitions of Complex Order and Stock-Option Order

The Commission finds that the proposed definitions of complex order and stock-option order are consistent with the Act. The Commission believes that the new definitions could permit the electronic trading on CBOE of complex orders representing investment strategies that do not fall within the enumerated strategies in CBOE's current rule, including transactions designed to limit risk. The Commission notes that the proposed definitions of complex order and stock-option order are consistent with definitions included in the rules of another options exchange[68] and in CBOE Rule 6.80(4).[69] In addition, the Commission believes that the rule changes removing the limit on the number of legs that may be included in a complex order could provide greater flexibility and permit the electronic trading on CBOE of additional complex orders.

B. Execution of Stock-Option Orders

1. Legging of Stock-Option Orders

The Commission believes that the proposal to revise CBOE Rule 6.53C, Interpretation and Policy .06 to provide for the execution of stock-option against other stock-option orders through COB and COA, rather than by legging against individual orders and quotes in the CBOE and CBSX EBooks, is consistent with the Act because it could facilitate the execution of stock-option orders. The Commission notes that another options exchange similarly permits stock-option orders traded on its electronic trading platform to execute only against other stock-option orders.[70]

The Commission also believes that it is consistent with the Act for CBOE to retain the legging feature for eligible market stock-option orders that cannot be executed, in full or in a permissible ratio, at the conclusion of a COA because the legging functionality could provide an additional opportunity for these orders to be executed. The Commission notes that CBOE believes

[55] *See id.*

[56] *See* CBOE Rule 6.53C, Interpretation and Policy .08(f)(2). AIM, SAM and CTC are mechanisms that may be used to cross two paired orders. *See* Notice, 77 FR at footnote 22.

[57] *See* CBOE Rule 6.53C, Interpretation and Policy .08(f)(2) and Notice, 77 FR at 10030.

[58] *See* CBOE Rule 6.53C, Interpretation and Policy .08(f)(2).

[59] *See* CBOE Rule 6.53C, Interpretation and Policy .08(a) and Notice, 77 FR at 10030–10031.

[60] *See id.*

[61] *See* Notice, 77 FR at 10031.

[62] *See* CBOE Rule 6.53C, Interpretation and Policy .04(b).

[63] *See* Notice, 77 FR at 10031.

[64] *See id.*

[65] *See* Notice, 77 FR at 10031–10032.

[66] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[67] 15 U.S.C. 78f(b)(5).

[68] *See* ISE Rule 722(a)(1) and (2).

[69] CBOE Rule 6.80(4) defines a Complex Trade for purposes of CBOE Chapter VI, Section E, ''Order Protection; Locked and Crossed Markets.'' CBOE Rule 6.81(b)(7) provides an exception from the prohibition on Trade-Throughs for any transaction that was effected as a portion of a Complex Trade.

[70] *See* Phlx Rule 1080, Commentary .08(a)(i) (stating that stock-option orders may only be executed against other stock-option orders and cannot be executed by the System against orders for the individual components).

that the eligibility parameters for eligible market stock-option orders could help to mitigate the risks that may be associated with legging stock-option orders.[71]

2. Eligible Market Orders

The Commission believes that it is consistent with the Act for CBOE to modify the eligible market order parameter in CBOE Rule 6.53C, Interpretation and Policy .06(d) by eliminating the provision that allows CBOE to establish an NBBO price parameter for such orders based on a maximum offer price for buy orders. CBOE states that it does not intend to use this parameter.[72] Accordingly, the Commission believes that eliminating this parameter will help to assure that the rule accurately reflects the parameters that CBOE may use to identify eligible market stock-option orders.

3. Communication of Stock Leg to a Designated Broker-Dealer(s)

As described more fully above, CBOE proposes to revise its rules to allow the Exchange to electronically communicate the stock leg of a stock-option order to a designated broker-dealer for execution on behalf of a Trading Permit Holder.[73] To participate in stock-option order automated processing, a Trading Permit Holder must enter into a brokerage agreement with one or more designated broker-dealers that are not affiliated with CBOE.[74]

The designated broker-dealer will act as agent for the stock leg of a stock-option order and will be responsible for the proper execution, trade reporting, and submission to clearing of the stock trade.[75] In addition, after CBOE communicates the paired stock orders to the designated broker-dealer for execution, the broker-dealer will be responsible for determining whether the orders may be executed in accordance with all of the rules applicable to the execution of equity orders, including compliance with the applicable short sale, trade-through, and reporting rules.[76] In addition, a Trading Permit Holder may submit a stock-option order only if the order complies with the QCT Exemption from Rule 611(a) of Regulation NMS, and a Trading Permit Holder submitting a stock-option order represents that the order complies with the QCT Exemption.[77] As described more fully in the Notice, CBOE's Hybrid System will validate compliance with the QCT Exemption with respect to each matched order communicated to the designated broker-dealer.[78]

CBOE states that this automated process for executing stock-option orders is not exclusive, and that Trading Permit Holders will continue to be able to use open outcry procedures to execute stock-option orders if they choose to do so.[79]

The Commission notes that CBOE's proposal to electronically communicate the stock leg of a stock-option order to a designated broker-dealer for execution is similar to rules adopted by other options exchanges.[80] In addition, the Commission notes that Trading Permit Holders will continue to have the ability to use open outcry procedures to execute stock-option orders if they choose to do so. Accordingly, the Commission finds that the proposal to allow CBOE to electronically communicate the stock leg of a stock-option order to a designated broker-dealer that is not affiliated with CBOE for execution on behalf of a Trading Permit Holder is consistent with the Act.

C. Allocation Algorithms and Priority

1. COB and COA Allocation Algorithms

Because stock-option orders generally will not execute against individual leg market interest in the CBOE and CBSX EBooks, CBOE is eliminating references in CBOE Rule 6.53C, Interpretation and Policy .06 to executions of stock-option orders against individual orders and quotes. Instead, stock-option orders in COB that are marketable against each other will execute automatically, and multiple stock-option orders at the same price will be allocated pursuant to the rules of trading priority otherwise applicable to incoming electronic orders in the individual component legs.[81] The Commission notes that this allocation provision for stock-option orders in COB is consistent with the existing complex order allocation provision in CBOE Rule 6.53C(c)(ii)(2).[82] Accordingly, the Commission believes that the allocation provision for marketable stock-option orders in COB is consistent with the Act.

Because CBOE will no longer permit the legging of stock-option orders in COA against individual orders and quotes in the component legs (except with respect to an eligible market stock-option order that cannot be executed following a COA), CBOE is amending the COA algorithm to eliminate the reference to executions against individual orders and quotes in the EBook, but retaining the remainder of the current stock-option order allocation algorithm in CBOE Rule 6.53C, Commentary .06(d). Accordingly, stock-option orders executed through COA will trade first at the best net price(s) and, at the same price, in the sequence set forth in CBOE Rule 6.53C(d)(v)(2)–(4).[83] The Commission believes that it is consistent with the Act for CBOE to continue to apply this allocation algorithm to stock-option orders.

2. Priority

For a stock-option order to execute against another stock-option order in COB or COA, the execution must occur at a price where the option leg(s) of the stock-option order have priority over the individual orders and quotes in CBOE's EBook.[84] To satisfy this condition, the individual options legs of the stock-option order: (1) Must not trade at a price that is inferior to CBOE's best bid (offer) in the individual component series; and (2) must not trade at CBOE's best bid (offer) in the individual component series if one or more public customer orders are resting at the best bid (offer) in each of the component series and the stock-option order could otherwise be executed in full or in a permissible ratio. These provisions are consistent with CBOE's existing priority rules,[85] and with the rules of other

[71] *See* Notice, 77 FR at 10028. Under CBOE Rule 6.53C, Interpretation and Policy .06(d), as amended, an "eligible market order" is a stock-option order that is within the designated size and order type parameters determined by CBOE on a class-by-class basis, and for which the NBBO is within designated size and price parameters, as determined by CBOE for the individual leg. The designated NBBO price parameters will be determined based on a minimum bid price for sell orders. CBOE may determine on a class-by-class basis to limit the trading times within regular trading hours that the legging functionality will be available.

[72] *See* Notice, 77 FR at footnote 16.

[73] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a).

[74] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a).

[75] *See* Notice, 77 FR at 10026–10027.

[76] *See* Notice, 77 FR at 10027.

[77] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a).

[78] *See* Notice, 77 FR at 10027.

[79] Stock-option orders may be represented in open outcry by floor brokers or by CBOE PAR officials. *See* Notice, 77 FR at footnote 9 and accompanying text. *See also* CBOE Rules 6.45A(b) and 6.45B(b).

[80] *See* ISE Rule 722, Supplementary Material .02. *See also* Phlx Rule 1080, Commentary .08.

[81] *See* CBOE Rule 6.53C, Interpretation and Policy .06(c). CBOE also could allocate stock-option orders pursuant to another allocation algorithm designated by CBOE under CBOE Rule 6.53C, Interpretation and Policy .09.

[82] CBOE Rule 6.53C(c) states that the allocation of complex orders in COB that are marketable against each other will be pursuant to the rules to trading priority otherwise applicable to incoming electronic orders in the individual component legs.

[83] *See* CBOE Rule 6.53C, Interpretation and Policy .06(d).

[84] *See* Notice, 77 FR at 10028.

[85] *See, e.g.,* CBOE Rules 6.45(e); 6.45A(b)(ii); and 6.45B(b)(ii).

options exchanges.[86] Accordingly, the Commission finds that the priority requirements for stock-option orders in CBOE Rule 6.53C, Commentary .06(b) are consistent with the Act.

D. Provisions Applicable to Marketable Stock-Option Orders

To the extent that a marketable stock-option order cannot be executed in full in, or in a permissible ratio, after it is routed to COB or following a COA, any part of the order that can execute will execute and the remaining balance will be routed on a class-by-class basis to PAR or, at the order entry firm's discretion, to the order entry firm's booth.[87] If the order is not eligible to route to PAR, the remaining balance will be cancelled.[88] The Commission believes that these provisions are consistent with the Act because they establish procedures for handling the remaining balance of a marketable stock-option order that cannot be executed in full or in a permissible ratio.

In addition, to the extent that a stock-option order resting in COB becomes marketable against the derived net market, the full order will be subject to a COA.[89] The Commission believes that this provision is consistent with the Act because it could facilitate the execution of a stock-option order that is marketable against the derived net market, but that would not execute against the derived net market because stock-option orders generally will not execute against leg market interest.

E. Price Check Parameters

The stock-option derived net market price check parameter in CBOE Rule 6.53C, Interpretation and Policy .08(f) will prevent the automatic execution of a stock-option order following a COA if the execution would not be within the acceptable derived net market that existed at the start of the COA. The Commission believes that this price check parameter is consistent with the Act because it could help to prevent the automatic execution of stock-option orders at extreme or potentially erroneous prices. The Commission believes that it is reasonable to use CBOE's best bid and offer for the individual series legs to calculate the acceptable derived net market for the option leg(s) of a stock-option order because the option leg(s) would not be permitted to trade at a price that is inferior to CBOE's best bid or offer. The Commission believes that using the NBBO for the stock, plus or minus an acceptable tick distance, to determine the acceptable derived net market for the stock leg of a stock-option order will provide CBOE with flexibility in setting this parameter. The Commission notes that a stock-option order submitted to the Hybrid System must comply with the QCT Exemption.[90] The stock leg of a stock-option order that complies with the QCT Exemption would be permitted to trade at a price that is outside the NBBO for the stock.

CBOE also proposes to extend the existing individual series leg width price check parameter in CBOE Rule 6.53C, Interpretation and Policy .08(a)(i), which currently applies to complex orders, to the individual series legs of market and marketable limit stock-option orders.[91] This price check parameter prevents the automatic execution of a marketable complex order when the width between CBOE's best bid and offer in any individual series leg is not within an acceptable price range. The Commission believes that it is consistent with the Act for CBOE to have the ability to apply this price check parameter to stock-option orders, in addition to complex orders.

F. Extension of the Re-COA Feature to Stock-Option Orders

CBOE proposes to amend CBOE Rule 6.53C, Interpretation and Policy .04(b) to apply its ''re-COA'' feature to stock-option orders resting at the top of the COB. For classes in which COA is activated, a non-marketable stock-option order resting at the top of the COB may be automatically subject to COA if the order is within a number of ticks away from current derived net market.[92] The Commission believes that applying the ''re-COA'' feature to stock-option orders could facilitate the execution of stock-option orders by providing an opportunity for a stock-option resting at the top of the COB to be executed automatically. Accordingly, the Commission finds that the provision is consistent with the Act.

G. Rule Text Reorganizations

The Commission believes that the proposed changes to reorganize, consolidate, and simplify CBOE Rule 6.53C, Interpretation and Policy .06 are consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[93] that the proposed rule change (SR–CBOE–2012–005) is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[94]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8783 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[86] *See, e.g.,* ISE Rule 722(b)(2); and NYSE Amex Rule 980NY, Commentary .03(d).

[87] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a)(1). As noted above, CBOE plans to file a separate proposal that will further describe booth routing parameters and order management terminal operations. *See* note 39, *supra.*

[88] *See id.*

[89] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a)(2). This system feature will not be applicable to a resting stock-option order that becomes marketable against another stock-option order(s).

[90] *See* CBOE Rule 6.53C, Interpretation and Policy .06(a).

[91] *See* CBOE Rule 6.53C, Interpretation and Policy .08(a)(5) and Notice, 77 FR at 10030—10031.

[92] *See* CBOE Rule 6.53C, Interpretation and Policy .04(b). CBOE will calculate the derived net market for a stock-option order using CBOE's best bid or offer in the individual option series leg(s) and the NBBO in the stock leg.

[93] 15 U.S.C. 78s(b)(2).

[94] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66758; File No. SR–NYSE–2012–05]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Granting Approval of a Proposed Rule Change Amending NYSE Rule 476A To Update its ''List of Exchange Rule Violations and Fines Applicable Thereto Pursuant to Rule 476A''

April 6, 2012.

I. Introduction

On February 7, 2012, New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Rule 476A to update its ''List of Exchange Rule Violations and Fines Applicable Thereto Pursuant to Rule 476A.'' The proposed rule change was published for comment in the **Federal Register** on February 24, 2012.[3] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change.

II. Description

By way of background, NYSE Rule 476 governs disciplinary proceedings involving charges against members, member organizations, principal

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 66421 (February 17, 2012), 77 FR 11181 (''Notice'').

executives, approved persons, employees, or others for violations of the federal securities laws, Exchange rules and agreements with the Exchange, and other offenses listed in the rule.

NYSE Rule 476A, ''Imposition of Fines for Minor Violation(s) of Rules,'' provides that, in lieu of commencing a disciplinary proceeding under Rule 476, the Exchange may (subject to specified requirements) ''impose a fine, not to exceed $5,000, on any member, member organization, allied member, approved person, or registered or non-registered employee of a member or member organization, for any violation of a rule of the Exchange, which violation the Exchange shall have determined is minor in nature.'' [4] The provisions of Rule 476A are known as the Exchange's Minor Rule Violation Plan.

According to the Exchange, the ''summary fines'' under Rule 476A provide a meaningful sanction for rule violations when the violation calls for stronger discipline than an admonition or cautionary letter, but the facts and circumstances of the violation do not warrant initiation of a formal disciplinary proceeding under Rule 476. A ''List of Exchange Rule Violations and Fines Applicable Thereto Pursuant to Rule 476A'' (''Rule 476A List'') is appended as Supplementary Material to the rule.

In the instant proposal, the NYSE proposes to amend the Rule 476A List to: (i) Make technical, non-substantive changes to conform the list to previously-approved changes in Exchange rules,[5] (ii) update the rules relating to conduct by Designated Market Makers (''DMMs''), and (iii) add rules relating to conduct by DMMs, as follows:

Proposed Non-Substantive Changes to Rule 476A List

The Exchange proposes to update the Rule 476A List to conform it to approved changes to Exchange rules by updating the titles of certain rules, updating references to rules that have been renumbered or harmonized with a Financial Industry Regulatory Authority (''FINRA'') rule, deleting references to rules that have been deleted, updating the descriptions of rules that have been amended, and fixing a typographical error.[6]

Proposed Updates to Rule 476A List for DMM Conduct Rules

The current Rule 476A List includes certain specific rules that govern DMM conduct (*e.g.,* NYSE Rules 104(a)(1)(A) and 104.10), as well as a category designated as ''Exchange policies regarding procedures to be followed in delayed opening situations,'' which refers to policies relating to DMM conduct included in NYSE Rule 123D. The Exchange proposes generally to update the Rule 476A List with current rules governing DMM conduct. In particular, under the proposed rule change, the list would be amended to include, more expansively, ''Rule 104 requirements for the dealings and responsibilities of DMMs'' and ''Rule 123D requirements for DMMs relating to openings, re-openings, delayed openings, trading halts, and tape indications.'' Thus, additional elements of Rules 104 and 123D would be included in the Minor Rule Violation Plan, as further detailed below.

Rule 104

NYSE Rule 104 requires DMMs registered in one or more securities traded on the Exchange to engage in a course of dealings for their own account to assist in the maintenance of a fair and orderly market, insofar as reasonably practicable, by contributing liquidity when lack of price continuity and depth, or disparity between supply and demand exists or is reasonably to be anticipated.[7]

The Rule 476A List currently includes the following elements of Rule 104:

- Rule 104(a)(1)(A), which requires DMMs to maintain a bid or an offer at the National Best Bid and National Best Offer (''inside'') at least 15% of the trading day for securities in which the DMM unit is registered that have a consolidated average daily volume of less than one million shares, and at least 10% for securities in which the DMM unit is registered that have a consolidated average daily volume equal to or greater than one million shares; and
- Rule 104.10, which is described in the Rule 476A List as relating to ''Functions of DMM.'' This description does not relate to the rule currently denominated as Rule 104.10, which was adopted when the Exchange adopted the New Market Model,[8] but to a former rule relating to certain subject matters that, according to the Exchange, continue to be covered in the current Rule 104.

The proposed rule change would, instead, include a single reference in the Rule 476A List identifying ''Rule 104 requirements for the dealings and responsibilities of DMMs'' as subject to the Minor Rule Violation Plan. The proposed rule change would have the effect of adding to the Rule 476A List Rules 104(b), (c), (d), and (e),[9] as well as Rule 104(a)(1)(B), the rule that governs the DMM's new pricing obligations, which were implemented by all equities markets on December 6, 2010.[10]

Rule 123D

The Rule 476A List currently provides that ''violations of Exchange policies regarding procedures to be followed in delayed opening situations'' are eligible for summary fines under the Minor Rule Violation Plan. According to the Exchange, such Exchange policies are codified in Rule 123D. Accordingly, the Exchange proposes to delete ''violations of Exchange policies regarding procedures to be followed in delayed opening situations'' and replace it with ''Rule 123D requirements for DMMs relating to openings, re-openings, delayed openings, trading halts, and tape indications.'' The effect of this change would be to include other requirements of DMMs set forth in Rule 123D—relating to openings, re-openings, trading halts, and tape indications—in the Minor Rule Violation Plan.

---

[4] NYSE Rule 476A(a).

[5] In addition to these technical changes to the Rule 476A List, which are described below, the proposed rule change would amend Rule 476A(a) by replacing the term ''allied member'' with the term ''principal executive,'' to be consistent with a prior rule change eliminating the category of ''allied member'' on the Exchange. *See* Securities Exchange Act Release No. 58549 (September 15, 2008), 73 FR 54444 (September 19, 2008) (SR–NYSE–2008–80). *See also* NYSE Rule 476, which uses the term ''principal executive.''

[6] For a more detailed description of these proposed non-substantive changes, *see* Notice, *supra* note 3.

[7] NYSE Rule 104 currently operates on a pilot basis, set to end on July 31, 2012. The Exchange stated its belief that the Rule 476A List should reference those rules that are currently operational, even if operating on a pilot basis.

[8] *See* Securities Exchange Act Release No. 58845 (October 24, 2008), 73 FR 64379 (October 29, 2008) (SR–NYSE–2008–46).

[9] *See* Notice, *supra* note 3 at 11182–83 for a full description of the elements of Rule 104 that, under the proposal, would be included in the Minor Rule Violation Plan. The Exchange states that other elements of Rule 104 (*i.e.,* Rule 104(j) and supplementary material .05 and .10) are not related to DMM obligations, but rather reflect operational aspects of the Exchange. *See id.* at note 11. The Exchange notes that, in a separate filing, it has proposed to delete NYSE Rule 104(a)(6). *See* Securities Exchange Act Release No. 65736 (November 10, 2011), 76 FR 71399 (November 17, 2011) (SR–NYSE–2011–56). The Commission instituted proceedings to determine whether to disapprove SR–NYSE–2011–56. *See* Securities Exchange Act Release No. 66397 (February 15, 2012), 77 FR 10586 (February 22, 2012).

[10] *See* Securities Exchange Act Release No. 63255 (November 5, 2010), 75 FR 69484 (November 12, 2010) (SR–NYSE–2010–69).

III. Discussion and Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[11] In particular, the Commission believes that the proposed rule change is consistent with Section 6(b)(5) of the Act [12] because expanding the list of DMM obligations that are subject to the Minor Rule Violation Plan should afford the Exchange increased flexibility in carrying out its supervisory responsibilities, and, in doing so, help to meet the aim of protecting investors and the public interest.

The Commission also believes that the proposed rule change is consistent with Sections 6(b)(1) and 6(b)(6) of the Act,[13] which require that an exchange enforce compliance with, and have rules that provide appropriate discipline for violations of, the Act, the rules and regulations thereunder, and Exchange rules. As an initial matter, the proposed rule change will further these objectives through its clarification of the list of Exchange rule violations that are subject to NYSE Rule 476A by updating rule titles and rule references, deleting references to rules that have been deleted, updating descriptions of rules that have been amended, and fixing a typographical error.

Further, the Commission recognizes that the proposed rule change will render violations of DMM obligations under Rule 104 [14] and Rule 123D that were not previously on the Rule 476A List as now eligible for treatment as minor violations. However, the Commission notes that designating a rule as subject to the Minor Rule Violation Plan does not signify that violation of the rule will always be deemed a minor violation. As noted by the Exchange, Rule 476A preserves the Exchange's discretion to seek formal discipline, as warranted, when transgressions of rules designated as eligible for the Minor Rule Violation Plan are found to be more serious. Thus, the Exchange will remain able to require, on a case-by-case basis, formal disciplinary action for any particular violation. Therefore, the Commission believes that the proposed rule change will not compromise the Exchange's ability to seek more stringent sanctions for the more serious violations of Rules 104 and 123D.

In addition, because NYSE Rule 476A provides procedural rights to a person fined under the rule, entitling the person to contest the fine and receive a full disciplinary proceeding,[15] the Commission believes that NYSE Rule 476A, as amended by this proposed rule change, will provide a fair procedure for the disciplining of Exchange members and persons associated with members, consistent with Sections 6(b)(7) and 6(d)(1) of the Act.[16]

Finally, the Commission finds that the proposed rule change is consistent with the public interest, the protection of investors, or is otherwise in furtherance of the purposes of the Act, as required by Rule 19d–1(c)(2) under the Act,[17] which governs minor rule violation plans. The Commission believes that the proposed changes to NYSE Rule 476A will strengthen the Exchange's ability to carry out its oversight and enforcement responsibilities as a self-regulatory organization, in cases where full disciplinary proceedings are unsuitable in view of the nature of a particular violation.

In approving this proposed rule change, the Commission emphasizes that in no way should the amendment of the rule be seen as minimizing the importance of compliance with NYSE rules and all other rules subject to the imposition of fines under NYSE Rule 476A. The Commission believes that the violation of any self-regulatory organization's rules, as well as Commission rules, is a serious matter. However, NYSE Rule 476A provides a reasonable means of addressing rule violations that do not rise to the level of requiring formal disciplinary proceedings, while providing greater flexibility in handling certain violations. The Commission expects that the Exchange will continue to conduct surveillance with due diligence and make a determination based on its findings, on a case by-case basis, of whether a violation requires formal disciplinary action under Rule 476.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[18] that the proposed rule change (SR–NYSE–2012–05) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8782 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[11] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78f(b)(1) and 15 U.S.C. 78f(b)(6).

[14] The Commission believes that it is appropriate to include in NYSE Rule 476A references to rules that are currently operating on a pilot basis.

[15] *See* NYSE Rule 476A(d).

[16] 15 U.S.C. 78f(b)(7) and 15 U.S.C. 78f(d)(1).

[17] 17 CFR 240.19d–1(c)(2).

[18] 15 U.S.C. 78s(b)(2).

[19] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(44).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66757; File No. SR–Phlx–2012–45]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Rebates for Adding and Removing Liquidity in SPY

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 thereunder,[2] notice is hereby given that on April 2, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section I [3] of its Pricing Schedule to further incentivize market participants to transact SPDR S&P 500 (''SPY'') [4] options.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Section I of the Exchange's Pricing Schedule is entitled ''Rebates and Fees for Adding and Removing Liquidity in Select Symbols.''

[4] SPY is one of the Select Symbols subject to the rebates and fees in Section I. A complete list of Select Symbols is included in Section I of the Pricing Schedule.

concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to further incentivize Customers who transact Complex Orders in SPY. The Exchange currently pays a Customer Complex Order Rebate for Adding Liquidity of $0.32 per contract and a Customer Complex Order Rebate for Removing Liquidity of $0.06 per contract. The Exchange is proposing to amend Section I of the Pricing Schedule to specify that the Exchange will increase the Customer Complex Order Rebates for Adding and Removing Liquidity by $0.01 per contract for transactions in SPY. Therefore, Customer Complex Orders that add liquidity in SPY will receive a rebate of $0.33 per contract and Customer Complex Orders that remove liquidity in SPY will receive a rebate of $0.07 per contract.

2. Statutory Basis

The Exchange believes that its proposal to amend its Pricing Schedule is consistent with Section 6(b) of the Act [5] in general, and furthers the objectives of Section 6(b)(4) of the Act [6] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities.

The Exchange's proposal to further incentivize Customers who transact Complex Orders in SPY is reasonable because Customer Complex Orders are becoming an increasingly important segment of options trading. The Exchange believes that it is reasonable to further incentivize Customer Complex Orders by offering a $0.01 per contract incentive for SPY options in addition to the Customer Complex Order Rebates for Adding and Removing Liquidity because the Exchange seeks to incentivize market participants to direct and transact a greater number of Customer Complex Orders at the Exchange, particularly in SPY. Creating these incentives and attracting Customer Complex Orders to the Exchange, in turn, benefits all market participants through increased liquidity at the Exchange. The Exchange's proposal to further incentivize Customers who transact Complex Orders in SPY is equitable and not unfairly discriminatory because the Exchange will uniformly pay an additional $0.01 per contract incentive in addition to the Customer Complex Order Rebates for Adding and Removing Liquidity to all Customer Complex Orders in SPY that receive the rebates.

Further, the Exchange also believes it is reasonable, equitable and not unfairly discriminatory to only offer rebates to Customers and not other market participants because Customer Complex Order flow brings unique benefits to the marketplace in terms of liquidity and order interaction. It is an important Exchange function to provide an opportunity to all market participants to trade against Customer Complex Orders.

In addition, the Exchange believes that paying an additional $0.01 per contract incentive in addition to the Customer Complex Order Rebates for Adding and Removing Liquidity in SPY, as compared to other option symbols, is reasonable, equitable and not unfairly discriminatory because any market participant is able to transact a Customer Complex Order in SPY and receive the additional rebate incentive regardless of volume. There is no requirement to transact a certain volume of Customer Complex Orders to qualify for the additional $0.01 per contract rebate incentive. Further, options overlying SPY are the most actively traded equity and ETF option in the United States (U.S.), accounting for more than 15% of the total volume on any given day.[7] Because of the substantial volume opportunity, the Exchange believes this additional $0.01 per contract incentive for SPY, as compared to other symbols, would continue to attract volume to the Exchange and benefit all market participants.

The Exchange operates in a highly competitive market, comprised of nine exchanges, in which market participants can easily and readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Accordingly, the rebates paid by the Exchange must remain competitive with rebates offered by other venues and therefore must continue to be reasonable and equitably allocated to those members that opt to direct orders to the Exchange rather than competing venues.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[8] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–Phlx–2012–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2012–45. This file number should be included on the subject line if email is used. To help the Commission process and review your

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] For March 2012, SPY options accounted for 17.21% of the total listed equity and ETF options volume traded in the U.S.

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2012–45 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8781 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66756; File No. SR–Phlx–2012–43]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Rebates and Fees for Adding and Removing Liquidity in Select Symbols

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 28, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section I of the Exchange's Pricing Schedule entitled ''Rebates and Fees for Adding and Removing Liquidity in Select Symbols,'' specifically to remove various Select Symbols.[3]

While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on April 2, 2012.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the list of Select Symbols in Section I of the Exchange's Pricing Schedule, entitled ''Rebates and Fees for Adding and Removing Liquidity in Select Symbols'' in order to attract additional order flow to the Exchange.

The Exchange displays a list of Select Symbols in its Pricing Schedule at Section I, ''Rebates and Fees for Adding and Removing Liquidity in Select Symbols,'' which are subject to the rebates and fees in that section. The Exchange is proposing to delete the following symbols from the list of Select Symbols in Section I of the Pricing Schedule: Apple Inc. (''AAPL''); Citigroup, Inc. ('C''); JP Morgan Chase & Co. (''JPM''); Amazon.com, Inc. (''AMZN''); AT&T Inc. (''T''), Caterpillar, Inc. (''CAT''); Exxon Mobil Corporation Common (''XOM''); International Business Machines (''IBM''); and American Express Company Common (''AXP'') (collectively ''Proposed Deleted Symbols''). These Proposed Deleted Symbols would be subject to the rebates and fees in Section II of the Pricing Schedule entitled ''Equity Options Fees.''[4]

While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on April 2, 2012.

2. Statutory Basis

The Exchange believes that its proposal to amend its Pricing Schedule is consistent with Section 6(b) of the Act[5] in general, and furthers the objectives of Section 6(b)(4) of the Act[6] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities.

The Exchange believes that it is reasonable to remove the Proposed Deleted Symbols from its list of Select Symbols to attract additional order flow to the Exchange. The Exchange believes that applying the fees in Section II of the Pricing Schedule to the Proposed Deleted Symbols, including the opportunity to receive payment for order flow, will attract order flow to the Exchange.

The Exchange believes that it is equitable and not unfairly discriminatory to amend its list of Select Symbols to remove the Proposed Deleted Symbols because the list of Select Symbols would apply uniformly to all categories of participants in the same manner. All market participants who trade the Select Symbols would be subject to the rebates and fees in Section I of the Pricing Schedule, which would not include the Proposed Deleted Symbols. Also, all market participants would be uniformly subject to the fees in Section II, which would include the Proposed Deleted Symbols.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Select Symbols'' refers to the symbols which are subject to the Rebates and Fees for Adding and Removing Liquidity in Section I of the Exchange's Pricing Schedule.

[4] Section II includes options overlying equities, ETFs, ETNs, indexes and HOLDRs which are Multiply Listed.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[7] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–Phlx–2012–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2012–43. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2012–43 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8780 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66755; File No. SR–Phlx–2012–42]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing Fees

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 28, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend certain Customer Routing Fees to recoup costs incurred by the Exchange in routing to away markets and also create a new category of Routing Fees entitled ''Firm/Broker-Dealer/Market Maker'' fees.

While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated the proposed amendment to the ISE Select Symbols Customer Routing Fee to be operative on April 2, 2012. In addition, the Exchange has designated the new category ''Firm/Broker-Dealer/Market Maker'' to be operative on the same date that SR–Phlx–2012–41 becomes operative.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to recoup costs that the Exchange incurs for routing and executing certain Customer orders in equity and index options to the International Securities Exchange, LLC (''ISE'') and also to recoup costs related to a new category of Routing Fees entitled ''Firm/Broker-Dealer/Market Maker'' fees. The Exchange's Pricing Schedule at Section V, currently includes the following Routing Fees for

---

[7] 15 U.S.C. 78s(b)(3)(A)(ii).

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

routing Customer and Professional orders to away markets:

Exchange	Customer	Professional
NYSE AMEX	$0.11	$0.31
BATS	0.55	0.55
BOX	0.11	0.11
CBOE	0.11	0.31
CBOE orders greater than 99 contracts in RUT, RMN, NDX, MNX, ETFs, ETNs and HOLDRs	0.29	0.31
C2	0.55	0.56
ISE	0.11	0.29
ISE Select Symbols*	0.23	0.39
NYSE ARCA (Penny Pilot)	0.55	0.55
NYSE ARCA (Standard)	0.11	0.11
NOM	0.54	0.54
NOM (NDX and MNX)	0.56	0.56

*These fees are applicable to orders routed to ISE that are subject to Rebates and Fees for Adding and Removing Liquidity in Select Symbols. See ISE's Schedule of Fees for the complete list of symbols that are subject to these fees.

The Exchange is proposing to amend the ''ISE Select Symbols'' [3] Customer Routing Fee from $0.23 per contract to $0.31 per contract. ISE recently amended its ''taker'' fee for regular, or non-complex, Priority Customer orders in the Select Symbols, regardless of size, from $0.15 per contract to $0.20 per contract.[4] In addition to the ISE taker fee, the Exchange also incurs other routing costs which it seeks to recoup.

In May 2009, the Exchange adopted Rule 1080(m)(iii)(A) to establish Nasdaq Options Services LLC (''NOS''), a member of the Exchange, as the Exchange's exclusive order router.[5] NOS is utilized by the Exchange's fully automated options trading system, PHLX XL®,[6] solely to route orders in options listed and open for trading on the PHLX XL system to destination markets. Each time NOS routes to away markets NOS is charged a $0.06 clearing fee and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange currently recoups clearing and transaction charges incurred by the Exchange as well as certain other costs incurred by the Exchange when routing to away markets, such as administrative and technical costs associated with operating NOS, membership fees at away markets, and technical costs associated with routing.[7] While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated these changes to be operative on April 2, 2012.

The Exchange is also proposing to create a new category of Routing Fees entitled ''Firm/Broker-Dealer/Market Maker'' fees. The Exchange recently filed a rule change to expand the routing capabilities of certain options orders that are eligible for electronic routing to other market centers by PHLX XL. Currently, Rule 1080(m) states that PHLX XL will route only Customer [8] FIND [9] and SRCH [10] orders to away markets. The rule change seeks to add non-customer FIND orders as a new category of orders that are eligible for routing.[11] This amendment to Exchange Rule 1080(m) would permit Firm, Broker-Dealer and Market Maker orders to be eligible for routing to other market centers when the Exchange cannot execute such orders at the National Best Bid or Offer (''NBBO'').[12]

Specifically, the Exchange proposes to amend Section V of the Pricing Schedule to add a new category ''Firm/Broker-Dealer/Market Maker'' to correspond to the non-customer FIND orders that would be eligible for Routing upon the effectiveness of SR–Phlx–2012–41 and its proposed amendments to Rule 1080(m). The Exchange proposes to assess a fixed Routing Fee of $0.55 per contract applicable to all away markets. The Exchange has designated the new category ''Firm/Broker-Dealer/Market Maker'' to be operative on the same date that SR–Phlx–2012–41 becomes operative.

As with all fees, the Exchange may adjust these Routing Fees in response to competitive conditions by filing a new proposed rule change.

2. Statutory Basis

The Exchange believes that its proposal to amend its Pricing Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed ISE Customer Routing Fee for Select Symbols is reasonable because it seeks to recoup costs that are incurred by the Exchange when routing certain

[3] *See* ISE's Schedule of Fees for the complete list of symbols that are subject to these fees.

[4] *See* ISE's Schedule of Fees. *See also* Securities Exchange Act Release No. 66597 (March 14, 2012), 77 FR 16295 (March 20, 2012) (SR–ISE–2012–17).

[5] *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32).

[6] *See* SR–Phlx–2012–41. This proposal refers to ''PHLX XL'' as the Exchange's automated options trading system. In May 2009 the Exchange enhanced the system and adopted corresponding rules referring to the system as ''Phlx XL II.'' *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32). The Exchange intends to submit a separate technical proposed rule change that would change all references to the system from ''Phlx XL II'' to ''PHLX XL'' for branding purposes.

[7] The Exchange is therefore increasing the ISE Select Symbols Customer Routing Fee to $0.31 per contract to account for the $0.20 ISE taker fee, the $0.06 clearing cost and another $0.05 per contract associated with administrative and technical costs associated with operating NOS.

[8] SR–Phlx–2012–41 defined the term ''customer'' as a person or entity that is neither a broker-dealer nor a direct or indirect affiliate of a broker-dealer. The rule filing specifically states that the term ''customer'' includes a ''professional'' as defined in Exchange Rule 1000(b)(14).

[9] A FIND order is currently defined as an order that is routable upon receipt. A FIND order received during open trading that is not marketable against the PHLX best Bid/Offer ''PBBO'' or the Away Best Bid/Offer (''ABBO'') will be entered into the limit order book at its limit price. The FIND order will not be eligible for routing until the next time the option series is subject to a new Opening Process. *See* Exchange Rule 1080(m)(iv)(B).

[10] A SRCH order is an order that is routable at any time. A SRCH order received during open trading that is not marketable against the PBBO or the ABBO will be entered into the Phlx XLII book. Once on the book, the SRCH order is eligible for routing if it is locked or crossed by an away market. *See* Exchange Rule 1080(m)(iv)(C).

[11] *See* SR–Phlx–2012–41.

[12] Under the proposal, non-customer FIND orders would be treated in the same manner as customer FIND orders, except that non-customer FIND orders would not be eligible for routing during the Opening Process. The proposed Routing Fees would apply to all orders that are routed to an away market and would not apply to orders not eligible for routing.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

Customer orders to ISE on behalf of its members. Each destination market's transaction charge varies and there is a standard clearing charge for each transaction incurred by the Exchange along with other administrative and technical costs that are incurred by the Exchange. The Exchange believes that the proposed Routing Fee would enable the Exchange to recover the customer taker fees assessed by ISE, plus clearing and other administrative and technical fees for the execution of Customer orders routed to ISE. The Exchange also believes that the proposed Routing Fee is equitable and not unfairly discriminatory because it would be uniformly applied to all Customer orders that are routed to ISE and part of ISE's Select Symbols.

The Exchange believes that the proposed new category of Routing Fee ''Firm/Broker-Dealer/Market Maker'' and the fixed $0.55 per contract Routing Fee are reasonable because other options exchanges charge fees for non-Customer orders such as Firm, Broker-Dealer and Market Maker orders and these fees are consistently higher than fees for Customer orders.[15] The pricing on the various options exchanges for such orders varies significantly from exchange to exchange, with much more variation than for Customer orders. Accordingly, the Exchange is proposing a $0.55 per contract side Routing Fee in order to capture the majority of the transaction and clearing fees for Firm, Broker-Dealer and Market Maker orders, while making the Exchange's Routing Fees easier to calculate and predict for members whose proprietary orders are routed away. In addition, fixed Routing Fees are easier to comprehend by the members whose orders are routed away. There is no uncertainty and it is simpler for members acting as agent for other members to pass-through fees to its Customer. Currently, predicting, calculating and charging back ''pass-through'' fees is an unduly burdensome, expensive and complicated task for Exchange members whose orders are routed away. The fixed Routing Fees for Firm, Broker-Dealer and Market Maker orders should ease the burden, expense and complexity of this task. Furthermore, fixed fees are easier to manage and maintain for the Exchange, ensuring accurate billing and accounting. The Exchange believes that the proposed new category of Routing Fee ''Firm/Broker-Dealer/Market Maker'' and the fixed $0.55 per contract Routing Fees are equitable and not unfairly discriminatory because the Exchange would assess all Firm, Broker-Dealer and Market Maker orders, eligible for routing to any away market, the same fee.[16]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[17] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–Phlx–2012–42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2012–42. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2012–42 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8779 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[15] The NASDAQ Options Market LLC (''NOM'') assesses a fixed Routing Fee to its Firms and Market Makers of $0.55 per contract. *See* Chapter V, Section (2) of The NASDAQ Stock Market LLC's Rules. In addition, the Chicago Board Options Exchange Incorporated (''CBOE'') assesses non-customer orders, including voluntary professionals and professionals, routing fees of $0.50 per contract in addition to the customary CBOE execution charges. *See* CBOE's Fees Schedule.

[16] A market participant may mark an order ''DNR'' for do not route and therefore would not be subject to the fees noted herein. *See* Rules 1066(h) and 1080(m).

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66754; File No. SR–Phlx–2012–41]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing of Non-Customer Orders

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 27, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 1080(m), Order Routing, to expand the routing capabilities of certain options orders that are eligible for electronic routing to other market centers by the Exchange's fully automated options trading system, PHLX XL.®[3] Under the proposal, non-customer FIND orders (as defined below) that are received during open trading will now be eligible for routing to other market centers for execution.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to expand the routing capabilities of option orders that are eligible for routing to other market centers when the Exchange cannot execute such orders at the National Best Bid or Offer (''NBBO''), by making non-customer FIND orders eligible for routing during open trading. In addition, the Exchange is revising the definition of the term ''SRCH order'' to be clear that only customer SRCH orders will continue to be eligible for routing.

Current Rule

Currently, Rule 1080(m) states that the PHLX XL system will route only customer[4] FIND[5] and SRCH[6] orders to away markets. For purposes of this rule, the term ''customer'' includes a ''professional'' customer as defined in Exchange Rule 1000(b)(14).[7] FIND and SRCH Orders designated as available for routing are first checked by the PHLX XL system for available contracts for potential execution on the Exchange. After checking the PHLX XL system for available contracts, orders are sent to other available market centers for potential execution. When checking the book, the PHLX XL system seeks to execute at the price at which it would send the order to a destination market center. In situations where the Exchange's disseminated bid or offer is inferior to the NBBO price, the PHLX XL system will contemporaneously route an order marked as an Intermarket Sweep Order (''ISO'')[8] to each away market disseminating prices better than the Exchange's price, for the lesser of: (a) The disseminated size of such away markets, or (b) the order size and, if order size remains after such routing, trade at the Exchange's disseminated bid or offer up to its disseminated size. If contracts still remain unexecuted after routing, they are posted on the Exchange's limit order book. Whether and under what circumstances such unexecuted contracts are re-routed depends upon the order's status as a FIND or SRCH order, as defined above.[9]

The Proposal

The Exchange is proposing to add non-customer FIND orders as a new category of orders that are eligible for routing. Non-customer FIND orders would be eligible for routing only during open trading, and not during the Opening Process.[10] Customer FIND and SRCH orders received prior to the opening would continue to be treated as they are currently under the rule, *i.e.,* both are eligible for routing during the Opening Process.

Under the current rule and practice, a customer FIND order received during open trading that is not marketable against the PHLX Best Bid or Offer (''PBBO'') or the Away Best Bid or Offer (''ABBO'') is entered into the limit order book at its limit price. If the FIND order is marketable against the ABBO, it is routed to markets disseminating the ABBO. If the order still has remaining

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This proposal refers to ''PHLX XL'' as the Exchange's automated options trading system. In May 2009 the Exchange enhanced the system and adopted corresponding rules referring to the system as ''Phlx XL II.'' *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32). The Exchange intends to submit a separate technical proposed rule change that would change all references to the system from ''Phlx XL II'' to ''PHLX XL'' for branding purposes.

[4] For purposes of this proposal, the term ''customer'' means a person or entity that is neither a broker-dealer nor a direct or indirect affiliate of a broker-dealer.

[5] A FIND order is currently defined as an order that is routable upon receipt. A FIND order received during open trading that is not marketable against the PHLX best Bid/Offer ''PBBO'' or the Away Best Bid/Offer (''ABBO'') will be entered into the limit order book at its limit price. The FIND order will not be eligible for routing until the next time the option series is subject to a new Opening Process. *See* Exchange Rule 1080(m)(iv)(B).

[6] A SRCH order is an order that is routable at any time. A SRCH order received during open trading that is not marketable against the PBBO or the ABBO will be entered into the Phlx XLII book. Once on the book, the SRCH order is eligible for routing if it is locked or crossed by an away market. *See* Exchange Rule 1080(m)(iv)(C).

[7] The term ''professional'' means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). A professional will be treated in the same manner as an off-floor broker-dealer for purposes of Rules 1014(g)(except with respect to all-or-none orders, which will be treated like customer orders, except that orders submitted pursuant to Rule 1080(n) for the beneficial account(s) of professionals with an all-or-none designation will be treated in the same manner as off-floor broker-dealer orders), 1033(e), 1064.02 (except professional orders will be considered customer orders subject to facilitation), 1080(n) and 1080.08 as well as Options Floor Procedure Advices B–6, B–11 and F–5. Member organizations must indicate whether orders are for professionals. *See* Exchange Rule 1000(b)(14).

[8] An ISO is a limit order for an options series that is identified as an ISO when routed to an away market center and, simultaneously with the routing of the order, one or more additional ISOs, as necessary, are routed to execute against the full displayed size of any Protected Bid, in the case of a limit order to sell, or any Protected Offer, in the case of a limit order to buy, for the options series with a price that is superior to the limit price of the ISO, with such additional orders also marked as ISOs.

[9] *See supra* notes 5 and 6.

[10] *See* Exchange Rule 1017(l)(iii).

size after routing, it will be entered into the limit order book. Such FIND order, or its remainder, is not eligible for routing again until the next time the affected option series is subject to a new Opening Process. Under the proposal, non-customer FIND orders would be treated in the same manner as customer FIND orders, except that non-customer FIND orders would not be eligible for routing during the Opening Process. The Exchange is proposing to route only customer FIND orders during the opening process to ensure that customers retain priority respecting all liquidity available as part of the Opening Process whether that liquidity is on PHLX or on another exchange. During open trading this is not an issue because two FIND orders will not be received at precisely the same time; generally, a customer FIND order would always have priority over a non-customer FIND order.

Unlike the treatment of FIND orders, the treatment of SRCH orders is not subject to change under the proposal. Currently, Exchange Rule 1080(m) states that the PHLX XL system will route only customer FIND and SRCH orders. While the proposed rule change would expand routable FIND orders to include non-customer FIND orders, the proposal would re-define a SRCH order as a customer order that is routable at any time. The purpose of this change is to ensure that only customer SRCH orders continue to be eligible for routing. Just as today, non-customer SRCH orders will not be eligible for routing. Non-customer orders received that are designated as SRCH orders will be placed on the limit order book if not executed on the Exchange upon receipt.

The Exchange notes that very few customers use the SRCH order type. Additionally, the Exchange has noted that there is no demand for the use of SRCH orders on the part of non-customers, as these participants tend to be sensitive to, and prefer to control, the charges incurred when their order is routed. The Exchange believes, however, that non-customers submitting their orders to the Exchange will use FIND orders. FIND orders allow participants to access potential liquidity on away markets while enabling them to manage expectations of the number of times their orders are routed. This helps participants to plan for and ascertain the fees they would incur each time their order is routed. Thus, the Exchange believes that the expansion of the FIND order to non-customer participants is appropriate and useful in the processing of non-customer orders seeking the best execution in the marketplace as a whole.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general and with Section 6(b)(5) of the Act,[12] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by the Act matters not related to the purposes of the Act or the administration of the Exchange.

The Exchange believes that the proposed rule change is also consistent with Section 6(b)(8) of the Act [13] in that it does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the proposal would expand the routing capabilities of certain orders that are eligible for routing to other exchanges, despite the fact that such other exchanges are competitors of the Exchange. This benefits investors because the Exchange's system will route to away markets at better prices.

The proposed rule change removes impediments to and perfects the mechanism of a free and open market and a national market system by enabling non-customer orders to have access to liquidity on other exchanges each time they submit a FIND order to the Exchange, providing for best executions in the national market system.

The Exchange further believes that the proposed rule change does not permit unfair discrimination between customers, issuers, brokers, or dealers. FIND orders submitted after the Opening Process, by either customers or non-customers, will be handled by the PHLX XL system in the same manner and will be provided with equal access to liquidity on other exchanges. This treatment of customer and non-customer FIND orders ensures that there is no unfair discrimination between customers and non-customers submitting such orders to the Exchange after the Opening Process.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78f(b)(8).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[14] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–Phlx–2012–41 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2012–41. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2012–41 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8778 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66765; File No. SR–NASDAQ–2012–043]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Establish the Market Quality Program

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 23, 2012, The NASDAQ Stock Market LLC (''NASDAQ'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by NASDAQ. On March 29, 2012, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1 thereto, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ (also known as the ''Exchange'') is filing with the Commission a proposal to add new Rule 5950 (Market Quality Program) to enable market makers that voluntarily commit to and do in fact enhance the market quality (quoted spread and liquidity) of certain securities listed on the Exchange to qualify for a fee credit pursuant to the Exchange's Market Quality Program, and to exempt the Market Quality Program from Rule 2460 (Payment for Market Making). NASDAQ believes this voluntary program will benefit investors, issuers or companies, and market participants by significantly enhancing the quality of the market and trading in such listed securities.

The Market Quality Program set forth in Rule 5950 will be effective for a one-year pilot period beginning from the date of implementation of the program. During the pilot, NASDAQ will periodically provide information to the Commission about market quality in respect of the Market Quality Program.

The text of the proposed rule change is available from NASDAQ's Web site at *http://nasdaq.cchwallstreet.com/Filings/,* at NASDAQ's principal office, on the Commission's Web site at *www.sec.gov,* and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the filing is to propose new Rule 5950 to enable Market Makers[4] that enhance the market quality of certain securities listed on the Exchange (known as ''targeted securities'') and thereby qualify for a fee credit pursuant to the Market Quality Program (''MQP'' or ''Program''), and to exempt the Program from Rule 2460.

Rule 5950 will be effective for a one-year pilot period. The pilot period will commence when the Market Quality Program is implemented by the Exchange and an MQP Company[5] and one or more related Market Makers are accepted into the MQP in respect of a security listed pursuant to the Program (''MQP Security'').[6] The pilot program will end one year after implementation.[7]

---

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange made a technical amendment to Item I of Exhibit 1 to delete an erroneous reference to the NASDAQ Options Market and replace it with a reference to the Exchange.

[4] The term ''Market Maker'' is defined in Rule 5005(a)(24) as a dealer that, with respect to a security, holds itself out (by entering quotations in the NASDAQ Market Center) as being willing to buy and sell such security for its own account on a regular and continuous basis and that is registered as such. Proposed Rule 5950(e)(5).

[5] The term ''MQP Company'' is defined in proposed Rule 5950(e)(7) as a fund (Exchange Traded Fund) sponsor or other entity that lists one or more MQP Securities on NASDAQ pursuant to the Market Quality Program. The term ''Company'' is defined in Rule 5005(a)(6) as the issuer of a security listed or applying to list on NASDAQ, and may include an issuer that is not incorporated, such as, for example, a limited partnership.

[6] The term ''MQP Security'' is defined in proposed Rule 5950(e)(1) as a security that meets all of the requirements to be listed on NASDAQ as an Exchange Traded Fund, Linked Security, or Trust Issued Receipt pursuant to Rules 5705, 5710, or 5720, respectively.

[7] The Exchange believes that, based on discussions with the Financial Industry Regulatory Authority (''FINRA''), FINRA intends to file an immediately effective rule change that would exempt from FINRA Rule 5250 Exchange programs that are approved by the Commission. The Exchange notes that FINRA Rule 5250 does not preclude the Exchange from any action, but precludes FINRA members (not all Exchange members are FINRA members) from directly or indirectly accepting payment or consideration from an issuer of a security for acting as a market maker. *See* Securities Exchange Act Release Nos. 60534 (August 19, 2009), 74 FR 44410 (August 28, 2009) (SR–FINRA–2009–036) (order approving proposal to adopt NASD Rule 2460 without substantive change into the Consolidated FINRA Rulebook as Rule 5250); and 38812 (July 3, 1997), 62 FR 37105 (July 10, 1997) (SR–NASD–97–29) (order approving adoption of NASD Rule 2460; FINRA Rule 5250 and NASDAQ Rule 2460 are based on NASD Rule 2460) (''1997 order''). Being mindful of the concern in the 1997 order about investor confidence and market integrity, the Exchange designed the MQP Program to be highly transparent with: clear public notification requirements; clear entry, continuation, and termination requirements; clear market maker accountability standards; and, perhaps most importantly, clear market quality (liquidity) enhancement standards that benefit investors and market participants.

During the pilot, the Exchange will periodically provide information to the Commission about market quality in respect of the MQP.

MQP Securities may include Exchange Traded Funds (''ETFs''), Linked Securities (''LS''), and Trust Issued Receipts (''TIRs'').[8] However, the Exchange believes that MQP Securities will predominantly, if not entirely, consist of ETFs as reflected in the proposal.

Background

The proposed Market Quality Program is a voluntary program designed to promote market quality in MQP Securities.[9] An MQP Company that lists an eligible MQP Security on NASDAQ will pay a listing fee as set forth in proposed Rule 5950 (''MQP Fee'') in addition to the standard (non-MQP) NASDAQ listing fee applicable to such MQP Security as set forth in the Rule 5000 Series (consisting of Rules 5000–5999).[10] An MQP Fee will be used for the purpose of incentivizing one or more Market Makers in the MQP Security (''MQP Market Maker'') to enhance the market quality of the MQP Security. Subject to the conditions set forth in this rule, this incentive will be credited (''MQP Credit'') to one or more MQP Market Makers that make a quality market in the MQP Security pursuant to the Program.[11]

The Need for the MQP

The Exchange believes that the MQP will be beneficial to the financial markets, to market participants including traders and investors, and to the economy in general. First, the Exchange proposes the MQP to encourage narrow spreads and liquid markets in situations that generally have not been, or may not be, conducive to naturally having such markets. The securities that comprise these markets may include less actively traded or less well known ETF products that are made up of securities of less well known or start-up companies as components.[12] Second, in rewarding Market Makers that are willing to ''go the extra mile'' to develop liquid markets for MQP Securities,[13] the MQP would clearly benefit traders and investors by encouraging more quote competition, narrower spreads, and greater liquidity. Third, the MQP will lower transaction costs and enhance liquidity in both ETFs and their components, making those securities more attractive to a broader range of investors. In so doing, the MQP will help companies access capital to invest and grow. And fourth, the MQP may attract smaller, less developed companies and investment opportunities to a regulated and transparent market and thereby serve the dual function of providing access to on-Exchange listing while expanding investment and trading opportunities to market participants and investors.

There is support for paid for market making (also known as ''PFMM'') at the highest governmental levels. Congressman Patrick McHenry, the Chairman of the House Committee on Governmental Reform and Oversight, for example, recently noted that agreements between issuers and market makers to pay for market making activity ''* * * would allow small companies to produce an orderly, liquid market for their stocks. Research has shown that these agreements, already permitted overseas, have led to a positive influence on liquidity for small public companies.''[14]

In a similar vein, Robert Greifeld, Chief Executive Officer of NASDAQ, recently noted that unlike the United States, ''[t]he U.K., Canada, and Sweden all have exchange markets that serve as 'incubators' for smaller companies.''[15] The Exchange believes that the MQP proposal will, by encouraging liquid markets, enable the Exchange to similarly serve as an ''incubator,'' and to continue being an innovator in expanding markets to benefit market participants, traders, and investors.[16]

The Exchange has a provision in its Rule 2460 that is, in respect of Exchange members, largely similar to FINRA Rule 5250. *See* Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131) (order approving registration of The NASDAQ Stock Market LLC as a national securities exchange and adopting Rule 2460). As discussed in the body of the proposal, the Exchange proposes to modify Rule 2460 so that it is not applicable to the MQP.

[8] For definitions of ETF, LS, and TIR, *see* proposed Rule 5950 subsections (e)(2), (e)(3), and (e)(4), respectively.

[9] The Exchange notes that MQP Securities do not encompass derivatives on such securities.

[10] The Rule 5000 Series contains rules related to the qualification, listing, and delisting of Companies on the NASDAQ Stock Market. The Rule 5100 Series discusses NASDAQ's general regulatory authority. The Rule 5200 Series sets forth the procedures and prerequisites for gaining a listing on the NASDAQ Stock Market, as well as the disclosure obligations of listed Companies. The Rule 5300, 5400, and 5500 Series contain the specific quantitative listing requirements for listing on the Global Select, Global Market, and Capital Market, respectively. The corporate governance requirements applicable to all Companies are contained in the Rule 5600 Series. Special listing requirements for securities other than common or preferred stock and warrants are contained in the Rule 5700 Series. The consequences of a failure to meet NASDAQ's listing standards are contained in the Rule 5800 Series. Finally, listing fees are described in the Rule 5900 Series.

[11] The enhanced market quality (*e.g.,* liquidity) would, as discussed below, emanate from market quality standards for MQP Market Makers that include, for example, posting a market in an MQP Security that is no wider on the offer side and no wider on the bid side than 2% away from NBBO. Proposed Rule 5950(c)(1)(B).

Other markets have considered various ways to increase liquidity in low volume securities. NYSE Euronext, for example, has advocated that a market-wide pilot program with wider spread increments for less liquid securities could be a worthwhile experiment. NYSE Euronext has also recognized that the creation of a program in which small companies could enter into agreements directly with broker-dealers or through exchanges to provide direct payments to a broker-dealer who agrees to make a market in the issuer's security is an idea that may warrant further review by FINRA and the Commission. *See* Testimony of Joseph Mecane, Executive Vice President, NYSE Euronext, Before the House Committee on Government Reform and Oversight, November 15, 2011.

[12] These small companies and their securities (whether components of listed products like ETFs or direct listings) have been widely recognized as essential to job growth and creation and, by extension, to the health of the economy. Being included in a successful ETF can provide the stocks of these companies with enhanced liquidity and exposure, enabling them to attract investors and access capital markets to fund investment and growth.

The Exchange expects, as noted, that MQP Securities will largely or entirely consist of ETFs, and discusses them accordingly in the proposal. The Exchange notes that the MQP is available and appropriate for LS and TIR products, which have some characteristics in common with ETF products. For example, TIRs are non-equity securities that are issued by a trust, and LS are non-equity securities that are linked to the performance of other assets, namely indexes and commodities (including currencies). *See* Rules 5710 and 5720.

[13] By imposing quality quoting requirements to enhance the quality of the market for MQP Securities, the MQP will directly impact one of the ways that Market Makers manage risk in lower tier or less liquid securities (*e.g.,* the width of bid and offer pricing).

[14] *See* Payments to Market Makers May Improve Trading in Smaller Stocks, by Nina Mehta, Bloomberg, November 15, 2011.

The Exchange believes that by establishing specific market quality requirements in the MQP to expand quote competition and liquidity in targeted securities such as ETFs, the Program will be conducive to capital formation—not only in the targeted securities or ETFs (*e.g.,* higher trading volume and/or creation of additional share units), but also in the individual components that make up the targeted securities (*e.g.,* higher share trading volume). Securities that trade in active, liquid markets are less likely to suffer from mispricing (that is, a discount in pricing because of a lack of liquidity) that can diminish a company's ability to raise capital for further investment and growth.

[15] *See* Robert Greifeld, CEO, NASDAQ OMX Group, Sarbox and Immigration Reform for Jobs, Wall Street Journal, October 4, 2011. For a discussion of capital formation issues in the U.S., *see* letters between Mary Shapiro, Chairman of the SEC, and Congressman Darrel E. Issa, Chairman of the House Committee on Oversight and Governmental Reform, dated March 22, 2011, April 6, 2011, and April 29, 2011.

[16] *See* Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness establishing the Investor Support Program to attract retail order flow to the Exchange). *See also* Securities Exchange Act Release No. 64437 (May 6, 2011), 76 FR 27710 (May 12, 2011) (NASDAQ–2010–059) (approval order creating a listing market, The BX Venture Market, that will have strict qualitative listing requirements

Continued

The MQP would reward Market Makers for committing capital to securities and meeting rigorous market quality benchmarks established by the Program.[17] This approach has worked very successfully in overseas markets, including the NASDAQ OMX Nordic First North market (known as ''First North'').

The practice of paid for market making to increase the liquidity of less liquid securities was examined by Johannes A. Skjeltorp and Bernt Arne Odegaard in a working paper from June 2011.[18] Skjeltorp and Odegaard examined paid for market making on the Oslo Stock Exchange, which uses a market making model that is similar to that of NASDAQ's First North market,[19] and noted that they ''* * * find a significant reduction in liquidity risk and cost of capital for firms that hire a market maker. Firms that prior to hiring a market maker * * * [have] a high loading on a liquidity risk factor, experience a significant reduction in liquidity risk to a level similar to that of the larger and more liquid stocks on the exchange.''

About six years prior to the Skjeltorp and Odegaard article, Amber Anand, Carsten Tanggaard, and Daniel G. Weaver studied liquidity provision through paid for market making on the Stockholm Stock Exchange (''SSE''), currently named NASDAQ OMX Stockholm AB.[20] The researchers examined the success of fifty previously illiquid firms that were listed on the SSE and enjoyed, along with investors, the benefits of paid for market making. The researchers examined the impact of the paid market maker program and found that firms experienced ''* * * a decreased cost of capital and significant improvements in market quality and price discovery.'' [21] The market makers were known as liquidity providers, and the firms could set maximum spread widths for their stocks, as is currently done. Anand, Tanggaard, and Weaver found that following the beginning of paid for market making services, spreads narrowed by a statistically significant amount and depth increased at the inside and in the aggregate for four price levels away from the inside. The researchers found that accompanying the increase in depth was a significant increase in average trade size, suggesting that traders did not find it necessary to break up their orders to accommodate low market depth, and found an increase in trading activity, suggesting that liquidity providers were actively trading with public customers.

More recently, Eric Noll, Executive Vice President, NASDAQ OMX Group, described the positive impact of paid for market making in the First North market, stating that NASDAQ OMX has had ''great success'' in increasing liquidity in stocks on First North, a European venue for smaller companies that has a program enabling companies to compensate market makers.[22] Mr. Noll noted that in just five years, First North market has grown to 141 listings with a total capitalization of 2.8 billion Euros, and that 22 of the First North companies have graduated to the main market since 2006.[23]

Paid for Market Making on the First North Market

The Exchange believes that commensurate with the previously-discussed studies regarding paid for market making,[24] it is instructive to examine the paid for market making experience on the First North market.

By way of background, the First North market is an alternative listing market to the NASDAQ OMX Nordic Main Market (''Main Market'').[25] Both First North and Main Market are subject to and regulated by European Union (''EU'') directives [26] and exchange rules, and are supervised and regulated by one or more Financial Services Authorities (''FSAs'').[27] While the Main Market is intended for listing companies that are well established, First North is intended for listing small, young or growth companies (not unlike the beneficiaries of the MQP) while providing an infrastructure and trading and settlement systems that are similar to those of the Main Market. First North offers new or small public companies the benefits of listing on a public market and the potential for good markets through a paid for market making system, and is often the first step towards listing on the Main Market.[28]

The First North paid for market making system is based on a standard exchange-supplied contract between a listing firm and a designated market maker (''DMM'') that sets forth market obligations for the market maker. The Exchange sets forth obligations for the MQP Market Makers (as well as MQP Companies) in proposed Rule 5950 in the belief that this provides the greatest amount of transparency and accountability for all that wish to participate in the MQP.

The paid for market making model on NASDAQ's First North has operated since 2002 and has been demonstrably successful to the benefit of issuers and investors, without material regulatory issues. One of the definitive market quality attributes associated with expansion of liquidity through paid for market making is the significant narrowing of bid/ask spreads. This

and quantitative standards that would attract smaller, growth companies).

[17] *See* Testimony of Edward S. Knight, General Counsel and Executive Vice President, NASDAQ OMX Group, Before the Senate Committee on Banking, Housing, and Urban Affairs, December 1, 2011.

[18] *See* Why do Firms Pay for Market Making in Their Own Stock? by Johannes A. Skjeltorp, Norges Bank, and Bernt Arne Odegaard, University of Stavanger and Norges Bank, June 2011. *See also* Why Designate Market Makers? Affirmative Obligations and Market Quality by Hendrik Bessembinder, Jia Hao, and Michael Lemmon, June 2011. This study suggests that future flash crashes can be avoided and social welfare enhanced by designating market makers and engaging paid for market making, and observing the positive attributes of direct payments from listed firms to designated market makers on the Stockholm Stock Exchange and Euronext Paris.

[19] The Exchange believes that the Skjeltorp and Odegaard article is therefore directly applicable to the First North paid for market making experience.

[20] *See* Paying for Market Quality, Working Paper F–2006–06, by Amber Anand, Carsten Tanggaard, and Daniel G. Weaver: November 2005, Aarhus School of Business.

[21] At the time of the study, SSE was owned by OMX AB. SSE merged into NASDAQ OMX in 2005 and retained its identity within the new corporate structure. The SSE paid for market making system matured into the current First North market.

[22] *See* Payments to Market Makers May Improve Trading in Smaller Stocks, by Nina Mehta, Bloomberg, November 15, 2011.

[23] *See* Testimony of Eric Noll, Executive Vice President, NASDAQ OMX Group, Before the House Committee on Government Reform and Oversight, November 15, 2011. Mr. Noll noted also that one of the unintended consequences of market fragmentation in the current U.S. securities markets has been a lack of liquidity and price discovery in listed securities outside of the top 100 traded names, and a disturbing absence of market attention paid to small growth companies by market participants. The Exchange believes that the MQP proposal offers a practical and positive solution.

[24] *See supra* notes 18, 19, and 20.

[25] NASDAQ OMX Nordic, which has securities exchanges and clearing operations in the Nordic countries Sweden, Denmark, Iceland, and Finland and Baltic countries Latvia and Estonia, operates First North and the Main Market. For additional information, *see http://www.nasdaqomxnordic.com/about_us?languageId=1.*

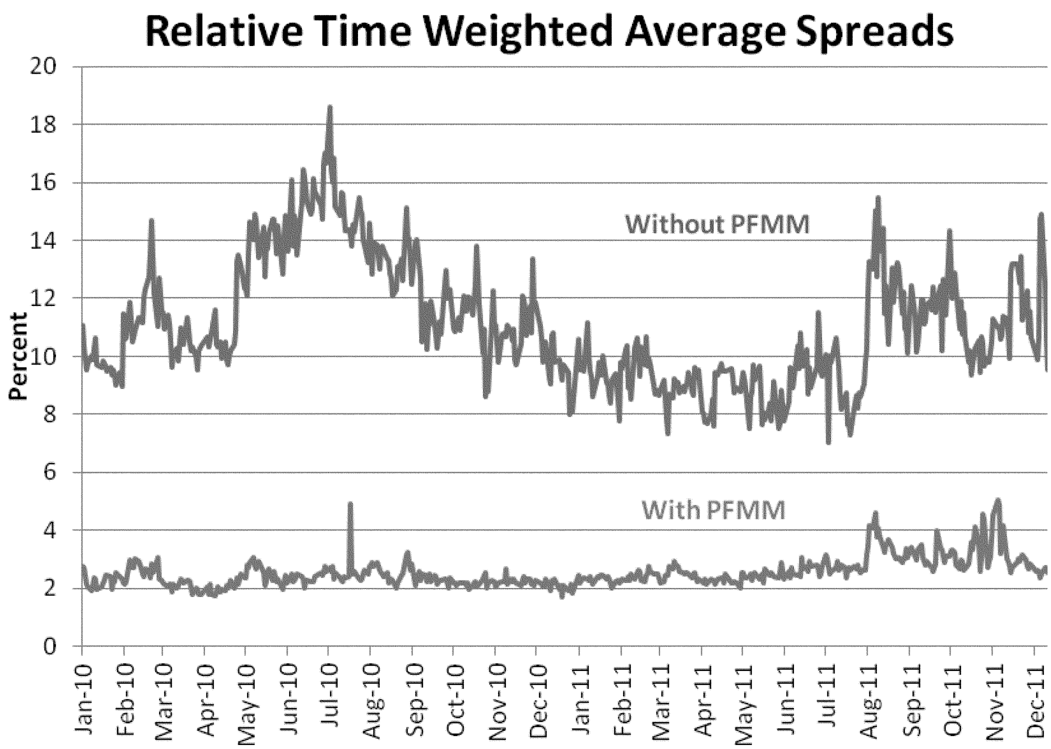
[26] For example, the Markets in Financial Instruments Directive (''MiFID''). It should be noted that certain parts of the EU legislation, for example the Transparency Directive, only apply to companies admitted to trading on the Main Market.

[27] A Financial Services Authority is the regulator of financial services and securities exchanges in an EU country (including the Nordics) and as such is similar to the Commission in respect of involvement in market regulation and oversight.

[28] The First North and Main Market have increasingly higher listing standards, similarly to the tiered NASDAQ listings markets. *See* Rule 5300, 5400, and 5500 Series regarding the Global Select, Global Market, and Capital Market, respectively. In a similarly tiered fashion, between First North and Main Market is an intermediary market known as First North Premiere (a segment of First North) that is designed to help companies seeking higher investor visibility and/or preparation for Main Market listing.

phenomenon is directly and immediately beneficial for all market participants, including investors and listing companies (which may also benefit from accompanying volume increase). As depicted in the chart below, in 2010 and 2011 the Relative Time Weighted Average Spread (''RTWAS'') [29] at First North was significantly better for securities with PFMM than for those without the benefit of PFMM.

The substantial positive advantage that market participants receive from PFMM is clearly demonstrated in the chart below, showing that non-PFMM security spreads were: (a) Often more than four times wider than PFMM security spreads; and (b) a majority of the time more than three times wider than PFMM spreads. Moreover, the spreads for stock with PFMM were more stable through time.



A comparison of Relative Time Weighted Average Spread on First North shows the significant, consistent impact of PFMM in narrowing spreads.[30] This directly benefits investors in PFMM securities by lowering their transaction costs.[31]

In terms of regulation, the First North PFMM experience has not raised concerns. Based on Exchange discussions with the Office of General Counsel at NASDAQ OMX Nordic in respect of the First North market, the Exchange is not aware of regulatory oversight issues (*e.g.,* Swedish FSA or Danish FSA) in respect of paid for market making on First North.[32]

The Exchange believes that the MQP will, like paid for market making on First North, achieve positive results.[33]

The Proposal—Background

The Exchange believes that this proposal would help raise investor and issuer confidence in the fairness of their transactions and the markets in general by enhancing market maker quote competition in securities on the Exchange, narrowing spreads, increasing shares available at the inside, reducing transaction costs, supporting the quality of price discovery, promoting market transparency, and improving investor protection.[34]

As noted, the proposal would enhance the market quality of targeted

[29] RTWAS is the bid/ask spread relative to the stock price calculated at every NBBO change, then averaged with weights for how long each NBBO condition lasted.

[30] The Exchange believes that the volatility reflected on the RTWAS chart after August 2011 is due in large part to economic events in the EU.

[31] The Exchange believes that just as First North's positive PFMM experience is successful in its own right, so it is equally positive within the wider European liquidity enhancement (paid for market making) experience. *See, e.g.,* How Do Designated Market Makers Create Value for Small-Caps? by Albert J. Menkveld and Ting Wang, August 1, 2011. This analysis of the 2001 Euronext system roll-out to the Amsterdam market, where small-caps had the opportunity to hire a DMM who guaranteed a minimum liquidity supply in their stock, found an improvement in liquidity level and a reduction in liquidity risk. *See also* Designated Sponsors and Bid-Ask Spreads on Xetra by Jördis Hengelbrock, October 31, 2008. This analysis of Deutsche Börse Group's Xetra program that began in the 1990s, where issuers of less liquid stocks could contract with a Designated Sponsor to provide liquidity in a stock for a fee, found that investor costs including spreads were lower for those stocks that had at least one such dedicated Designated Sponsor.

[32] Moreover, the Exchange notes that while spreads widened for stocks on all markets around the world during the height of the financial crisis in September and October 2008, First North stocks with PFMM experienced less spread widening than comparable stocks without PFMM.

[33] The Exchange believes that even though First North market lists equities while the proposed MQP market would emphasize listing ETF products, this does not detract from, and indeed enhances, the comparability of the First North PFMM experience to MQP. *See infra* note 36 (discussing the potential benefit of the unique trust structure of ETFs).

[34] The Commission has recognized the strong policy preference under the Act in favor of price transparency and displayed markets. *See* Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (Concept Release on Equity Market Structure).

To that end, the Exchange has recently put into place initiatives designed to expand the liquidity of certain targeted securities on transparent and displayed markets on the Exchange. *See, e.g.,* Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness of proposal to establish Investor Support Program in respect of retail or natural order flow).

securities, particularly ETFs. The Exchange believes that ETFs offer great value to retail and institutional investment communities, as reflected in their popularity as investment vehicles both in the U.S. and abroad.[35] ETFs offer transparency, liquidity, diversification, cost efficiency, and investment flexibility to gain broad market exposure or to express a directional view as a core or satellite component to one's investment portfolio, and do so while offering investment exposure to all asset classes—many of which would otherwise be inaccessible.[36] Moreover, ETFs, particularly those that are equity based, also benefit listed companies. By being included in a single, diversified security, companies gain access to a greater audience of investors who may not have bought the individual stock.[37] This means that the markets are deeper and more liquid, benefiting not only investors but the economy as a whole.[38] This proposal will allow ETFs that may not otherwise see much trading or volume [39] to be listed and traded on the Exchange in more liquid markets.[40]

The Proposal—Specifics

Proposed Rule 2460

Preliminarily, the Exchange is proposing to modify its Rule 2460, which prohibits direct or indirect payment by an issuer to a Market Maker, to indicate that Rule 2460 is not applicable to the MQP.[41] Specifically, the Exchange is proposing new IM–2460–1 (Market Quality Program) [42] to state that Rule 2460 is not applicable to a member that is accepted into the Market Quality Program pursuant to Rule 5950 or to a person that is associated with such member for their conduct in connection with that program. The Exchange believes that this proposed limited clarification is proper in that it allows the MQP to go forward on a pilot basis without denigrating the basic premise of Rule 2460, which was designed to forestall problematic relationships between exchange members (*e.g.,* market makers) and issuers. The Exchange's proposal, on the other hand, assiduously controls the exchange member/issuer relationship by setting forth an extensive rule-based process with clear Program requirements for issuers (MQP Companies) and clear market quality requirements for members (MQP Market Makers) that can only be effected in a lit and highly regulated exchange environment.

In the order approving NASD Rule 2460 (the 1997 order), upon which NASDAQ Rule 2460 is based (as is FINRA Rule 5250), the Commission discussed that NASD Rule 2460 preserved investor confidence, preserved the integrity of the marketplace, and established a clear standard of practice for member firms.[43]

The Exchange designed the MQP to meet the goals of market integrity, investor confidence, and clear member standards as discussed in the 1997 order. In particular, the Exchange designed the MQP to have precise standards for all parties in the Program (*e.g.,* MQP Companies and MQP Market Makers) and to be highly transparent with clear public notification requirements; with clear entry, continuation, and termination requirements; with clear Market Maker accountability standards; and, perhaps most importantly, with clear market quality (liquidity) enhancement standards that benefit investors and

[35] The Exchange notes that foreign (non-U.S.) ETFs, particularly those that are derivative-based, may have certain negative characteristics that are not present in U.S. ETFs. In some cases, under the Undertakings for Collective Investment in Transferable Securities (UCITS, Europe's equivalent of the Investment Company Act of 1940) structure, individual firms are permitted to fulfill multiple roles within the construct of the product's trading and or creation/redemption process (*e.g.,* the Sponsor/Issuer of a European ETF could be the same entity as the market maker, distributor, intraday Net Asset Value (''NAV'') calculation agent, custodian bank, and/or counterparty to any underlying asset). Under the Investment Company Act of 1940 (''1940 Act''), this is not permitted.

[36] It has been noted that since the prices of ETFs are generally linked back to the underlying securities, there is less opportunity for manipulation. *See* Payments to Market Makers May Improve Trading in Smaller Stocks, by Nina Mehta, Bloomberg, November 15, 2011. To that end, the Exchange notes that by definition an ETF will have an insulating wall between Market Maker and product, namely a trust structure—which is not present with other products such as equity securities—that establishes the daily NAV for an ETF. NAV reflects the per-share value of an ETF, which is based upon the performance of a fund's underlying components and methodology.

[37] *See* Testimony of Eric Noll, Executive Vice President and Head of Transaction Services NASDAQ OMX, before the Securities Subcommittee of the Senate Banking Committee October 19, 2011 (''I can tell you from personal experience that the companies that make up QQQ [(the NASDAQ–100 technology ETF)] consider it a real achievement, and certainly NASDAQ is proud of the excellence QQQ represents.'').

In addition, the Exchange believes that purchasers of ETFs that find success because of increased market quality (especially where such ETFs are smaller or niche funds with fewer components) may choose to invest directly in the fund components after a positive ETF market quality and execution experience.

[38] *See* Testimony of Eric Noll, Executive Vice President, NASDAQ OMX Group, before the House Committee on Oversight and Government Reform, November 15, 2011.

[39] There are a record 291 funds (216 ETFs and 75 ETNs) on the March 2012 ''ETF Deathwatch'' list maintained by Ron Rowland, president of Capital Cities Asset Management. All the funds on this list have limped along for at least three months with less than $5 million in assets or fewer than $100,000 worth of shares changing hands daily. The list now includes about 17% of the industry's approximately 1,400 ETFs and exchange-traded notes, as measured by number of funds. Mr. Rowland states: ''The largest risk is not, however, that [the funds] may close in the future. No, the more notable risk is that they suffer from extremely poor liquidity *today.* Wide bid/ask spreads, little to no volume behind the quotes, and sleeping market makers can potentially inflict much more damage on unknowing investors than a fund closure.''

[40] In that this proposal is designed to provide market quality support to smaller, less frequently traded segments of securities (ETFs), subsection (d) of proposed Rule 5950 indicates that an MQP Security will no longer be eligible to remain in the MQP if the security sustains an average NASDAQ daily trading volume (''ATV'') of two million shares or more for three consecutive months. Subsection (d) also provides other reasons for termination of the MQP with respect to an MQP security: an MQP Company withdraws from the MQP, is no longer eligible to be in the MQP, or ceases to make MQP payments to NASDAQ; an MQP Security is delisted or is no longer eligible for the MQP; an MQP Security does not have at least one MQP Market Maker for more than one quarter; or an MQP Security does not, for two consecutive quarters, have at least one MQP Market Maker that is eligible for MQP Credit. Any MQP Credits remaining upon termination of the MQP in respect of an MQP Security will be distributed on a pro rata basis to the MQP Market Makers that made a market in the MQP Security and were eligible to receive MQP Credit pursuant to this rule. If no MQP Market Makers qualify, then the remaining MQP Credit will be refunded to the MQP Company. Termination of an MQP Company, MQP Security, or MQP Market Maker does not preclude the Exchange from allowing re-entry into the Program where the Exchange deems proper. Proposed Rule 5950(d).

[41] *See* Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131) (order approving registration of The NASDAQ Stock Market LLC as a national securities exchange and adopting Rule 2460). FINRA, with whom the Exchange has an agreement regarding provision of certain regulatory services, has a similar provision in FINRA Rule 5250. As discussed, the Exchange believes that FINRA intends to file an immediately effective rule change that would exempt from FINRA Rule 5250 Exchange programs that are approved by the Commission.

[42] IM reflects interpretive material to an Exchange rule.

[43] *See* Securities Exchange Act Release No. 38812 (July 3, 1997), 62 FR 37105 (July 10, 1997) (SR–NASD–97–29) (order approving adoption of NASD Rule 2460). In discussing the 1997 order, the Commission cited to NASD Notice to Members 75–16 (February 20, 1975), and also to the letter from Kenneth S. Spirer, Attorney, Division of Market Regulation, SEC, to Mr. Jack Rubens, Monroe Securities, Inc. (May 4, 1973) (regarding acceptance of a fee or service charge from issuers in connection with making a market). *See also* Securities Exchange Act Release No. 39670 (February 25, 1998), File No. S7–3–98, 63 FR 9661) (notice for public comment of proposed amendments to Rule 15c2–11 under the Act in response to increasing incidents of fraud and manipulation in the OTC securities market involving thinly traded securities of thinly-capitalized issuers, known as microcap securities) (''15c2–11 proposal''). In the 15c2–11 proposal, the Commission cited NASD Rule 2460 when discussing that microcap fraud often involves ''pump and dump'' operations, in which unscrupulous brokers sell the securities of less-seasoned issuers to retail customers by using high pressure sales tactics and a supply of securities under the firm's control.

market participants. The positive aspects of the MQP are clear and unambiguous.[44]

First, the entire Market Quality Program is clearly and accurately set forth in proposed Rule 5950. This includes the application and withdrawal process, the listing fee and credit structure, the market quality standards that an MQP Market Maker must meet and maintain to secure an MQP Credit, and the Program termination process. Second, the Exchange will provide notification on its public Web site regarding the variable aspects of the Program. Specifically, this notification will include the names of the MQP Companies and the MQP Market Makers that are accepted into the Program; how many MQP Securities an MQP Company may have in the Program; the specific names of the MQP Securities that are listed pursuant to the Program; the identity of the MQP Market Makers in each MQP Security; and the amount of the supplemental MQP Fee, if one is established by an MQP Company, in addition to the basic MQP Fee, as discussed below. Third, MQP Securities will be traded on a highly regulated and transparent exchange, namely NASDAQ, pursuant to the current trading and reporting rules of the Exchange, and pursuant to the established market surveillance and oversight procedures of the Exchange. And fourth, the MQP would encourage narrower spreads and better market quality (more liquid markets) for securities that generally have not been, or may not be, conducive to naturally having such markets. The Exchange believes that these factors, which directly benefit all market participants and investors, are instrumental to developing strong investor confidence in the MQP and the integrity of the market.

Moreover, the Exchange believes that the MQP does not implicate conflicts of interest. That is, unlike the situation that the NASD was trying to address in its Rule 2460 or NASD Notice to Members 75–16, where issuers had the ability to directly pay a market maker to illegally pump up the price of an issuer's stock, the proposed MQP does not encourage MQP Market Makers to improperly pump up prices nor, for that matter, establish any direct financial connection between MQP Market Makers and MQP Companies. First, an MQP Company must go through an MQP application process, and the Exchange must accept the MQP Company into the Program, before an MQP Company can list a product pursuant to the Program.[45] Second, an MQP Market Maker must go through a separate MQP application process, and the Exchange must accept an MQP Market Maker into the Program, before an MQP Market Maker can make a market in a product listed pursuant to the Program.[46] Third, in terms of flow of funds, the Exchange stands between an MQP Company and an MQP Market Maker. An MQP Company cannot and does not, under any circumstances, pay any funds to an MQP Market Maker that makes a market in the MQP Company's product pursuant to the Program. This is crucial. The Program is constructed so that the only way that an MQP Market Maker can earn an MQP Credit—the payment of which is administered by the Exchange—is to maintain a quality market in terms of the spread and liquidity of an MQP Security.[47] The Program does not afford any other way for an MQP Market Maker to earn an MQP Credit. The Exchange firmly believes that the clear, unambiguous, and transparent nature of the Program and its established market quality standards are counter-indicative of any inherent conflict of interest.[48]

Additionally, the Exchange notes that the MQP is proposed initially as a pilot program. This is significant for several reasons. First, NASDAQ is proposing the pilot as an attempt to repair a gap in market structure, namely the challenge of certain small or start-up securities lacking access to quality markets with adequate liquidity.[49] Second, the Exchange has agreed, as part of the MQP pilot, to submit periodic reports to the Commission about market quality in respect of the MQP. These reports will endeavor to compare, to the extent practicable, securities before and after they are in the MQP. The reports will provide information regarding, for example, volume metrics, number of MQP Market Makers in target securities, and spread size, and will help the Commission and NASDAQ to evaluate the efficacy of the Program and the PFMM concept. And third, if the Exchange desires to expand the pilot program or make the MQP permanent, the Exchange will need to file a new rule change proposal with the Commission.

The Exchange believes that the MQP proposal would help raise investor and issuer confidence in the fairness of their transactions and the markets in general by enhancing market maker quote competition in securities on the Exchange, narrowing spreads, increasing shares available at the inside, reducing transaction costs, supporting the quality of price discovery, promoting market transparency, and improving investor protection.

Proposed Rule 5950—Securities Eligible for the MQP

The MQP is available to Companies that choose to list certain MQP Securities on the Exchange. To be eligible for listing, MQP Securities must meet the requirements to be listed on NASDAQ as an ETF, LS, or TIR pursuant to Rules 5705, 5710, and 5720, respectively.[50] In addition, the MQP Security must meet all NASDAQ requirements for continued listing during the period of time that the MQP Security is in the MQP.[51]

Proposed Rule 5950—Application and Withdrawal

The first step for an entity wishing to participate in the MQP by listing a security on the Exchange, and for a Market Maker wishing to participate in the MQP as an MQP Market Maker, is to submit an MQP application to the

[44] In addition to the clear and unambiguous MQP market quality standards promoting tighter markets and increased liquidity to the benefit of market participants, it has been demonstrated that already-established paid for market making programs in Europe have resulted in a significant and sustained reduction in spreads. As an example, securities that enjoyed PFMM in NASDAQ's First North's market have spreads that are as much as four times narrower, and are more stable, than securities without PFMM. *See supra* notes 30, 31, and 32 and related text. Narrower spreads always benefits [sic] investors by lowering their transaction costs.

[45] Moreover, an MQP Company approved to be in the Program must meet both the non-MQP initial and continued listing standards (*e.g.,* Rules 5300, 5400, 5500) and the MQP initial and continued listing standards to list a security pursuant to the MQP.

[46] Moreover, an MQP Market Maker must be approved to be a member on NASDAQ to be eligible for the MQP, and thereafter must attain the general market making requirements (*e.g.,* Rule 4613) and the specific MQP market quality standards to be able to attain an MQP Credit.

[47] One of the eligibility criteria for an MQP Market Maker to receive an MQP Credit, for example, is that the MQP Market Maker must maintain at least 2,500 shares of attributable, displayed posted liquidity on the NASDAQ Market Center that are priced no wider on the offer side and no wider on the bid side than 2% away from NBBO. Proposed Rule 5950(c)(1)(B).

[48] The Exchange notes that the MQP as proposed (*e.g.,* fully transparent and with clear market quality standards) would not be susceptible to the ''pump and dump'' fraud and manipulation schemes noted in the 15c2–11 proposal. *See also supra* note 36 discussing that ETFs afford less opportunity for manipulation and that the ETF trust structure acts as an insulating wall between market maker and product.

[49] These securities may include less actively traded or less well known ETF products that have less well known or start-up companies as components.

[50] The Exchange believes that the Companies most likely to list on the MQP, and pay the requisite MQP listing fees, will be ETF family sponsors.

[51] Proposed Rule 5950(b)(1).

Exchange.[52] Once the Exchange determines that the MQP Company and the MQP Market Maker are eligible to be in the MQP according to the parameters of the proposed rule, the Exchange will indicate acceptance to the MQP Company and the MQP Market Maker. NASDAQ will provide notification on its Web site regarding acceptance of an MQP Company and an MQP Market Maker into the Program.[53] NASDAQ may, on a Program-wide basis, limit the number of MQP Securities that any one MQP Company may list in the MQP; any limitation would be uniformly applied to all MQP Companies.[54] In determining to limit the number of MQP Securities in the MQP, NASDAQ may consider information that it believes will be of assistance to it, such as whether a restriction, if any, is in the best interest of NASDAQ, the MQP Company and the goals of the MQP, and investors.[55]

Moreover, to further enhance the transparency of the Program, proposed Rule 5950(a)(1)(C) indicates that NASDAQ will also provide notification on its Web site regarding the following: the total number of MQP Securities that any one MQP Company may have in the Program; and the names of MQP Securities that are listed on NASDAQ and the MQP Market Maker(s) in each listed MQP Security.

An MQP Company and an MQP Market Maker may choose to withdraw from the Program. After an MQP Company is in the MQP for six consecutive months but less than one year, it may voluntarily withdraw from the MQP on a quarterly basis. The MQP Company must notify NASDAQ in writing not less than one month prior to withdrawing from the MQP. NASDAQ may determine, however, to allow an MQP Company to withdraw from the MQP earlier.[56] After an MQP Company is in the MQP for one year or more, it may voluntarily withdraw from the MQP on a monthly basis. The MQP Company must notify NASDAQ in writing one month prior to withdrawing.[57] After an MQP Market Maker is in the MQP for not less than one quarter, he may withdraw from the MQP on a quarterly basis. The MQP Market Maker must, similarly to an MQP Company, notify NASDAQ in writing one month prior to withdrawing.[58]

After an MQP Company is in the MQP for one year, the MQP and all obligations and requirements of the Program will automatically continue on an annual basis unless NAQSAQ [sic] terminates the Program by providing not less than one month prior notice of intent to terminate; the MQP Company withdraws from the Program pursuant to subsection (a)(2) of this rule; or the MQP Company is terminated from the Program pursuant to subsection (d) of this rule.[59]

Proposed Rule 5950—MQP Fees From MQP Companies

An MQP Company seeking to participate in the MQP must pay to NASDAQ an annual basic MQP Fee of $50,000 per MQP Security. The basic MQP Fee must be paid in quarterly installments as billed by NASDAQ. The basic MQP Fee will be allocated as follows: 50% will fund the Quote Share Payment that is based on Qualified Quotes; and 50% will fund the Trade Share Payment that is based on Qualified Trades, as defined and described below.[60]

An MQP Company may also choose to pay an annual supplemental MQP Fee per MQP Security. The basic MQP Fee and supplemental MQP Fee when combined will not exceed $100,000 per year. The supplemental MQP Fee must be paid, together with the basic MQP Fee, in quarterly installments as billed by NASDAQ. The amount of the supplemental MQP Fee, if any, will be determined by the MQP Company on an annual basis. The supplemental MQP Fee must be paid, together with the basic MQP Fee, to NASDAQ in quarterly installments. An MQP Company shall indicate the proportions between 0% and 100% in which the supplemental MQP Fee will be allocated to the Quote Share Payment and/or Trade Share Payment. NASDAQ will provide notification on its Web site regarding the amount, if any, of the supplemental MQP Fee and the Quote Share Payment/Trade Share Payment allocation determined by an MQP Company.[61]

The MQP Fee is in addition to the standard (non-MQP) NASDAQ listing fee applicable to the MQP Security and does not offset such standard listing fee.[62]

The MQP Fee will be paid to the Exchange on a quarterly basis as billed by the Exchange, and will be credited to one or more MQP Market Makers that qualify for such credit for an MQP Security pursuant to proposed Rule 5950. NASDAQ will bill MQP Companies in arrears. NASDAQ will, at the beginning of a quarter, bill each MQP Company for the quarterly portion of an MQP Company's MQP Fee (basic and supplemental) for an MQP Security. Each such quarterly bill will be based on the MQP Credit that one or more MQP Market Makers in an MQP Security qualified for in the immediately preceding quarter pursuant to this rule.[63] All revenue from MQP Fees (basic and supplemental) will be credited pro rata to the eligible MQP

[52] *See* Proposed Rule 5950(a). Thus for an MQP Company to be liable for payment of MQP Fees pursuant to the Program, and for an MQP Market Maker to be eligible to receive an MQP Credit for his market making activities, the Exchange must have accepted the application of each of these parties in respect of an MQP Security, and, the parties must each have fulfilled their obligations pursuant to the MQP. Proposed Rule 5950(b)(1) and (c)(1).

[53] Proposed Rule 5950(a)(1)(C).

[54] NASDAQ may also, on a Program-wide basis, limit the number of MQP Market Makers permitted to register in an MQP Security. NASDAQ will provide notification on its Web site of any such limit. If a limit is established, NASDAQ will allocate available MQP Market Maker registrations in a first-come-first-served fashion based on successful completion of an MQP Market Maker application. Proposed Rule 5950(c)(3).

[55] Proposed Rule 5950(a)(1)(A) and (B). Factors that may be considered by the Exchange are set forth in subsection (a)(1)(B)(i) and include, but are not limited to, the following: the current and expected liquidity characteristics of MQP Securities; the projected initial and continuing market quality needs of MQP Securities; and the trading characteristics of MQP Securities (*e.g.,* quoting, trading, and volume).

[56] In making this determination, NASDAQ may take into account the volume and price movements in the MQP Security; the liquidity, size quoted, and quality of the market in the MQP Security; and any other relevant factors. Proposed Rule 5950(a)(2)(A).

[57] Proposed Rule 5950(a)(2)(B).

[58] Proposed Rule 5950(a)(2)(C).

[59] Proposed Rule 5950(a)(3).

[60] Proposed Rule 5950(b)(2)(A). Moreover, Trade Share Payments will be based upon each MQP Market Maker's share of total Qualified Trades in an MQP Security executed on the NASDAQ Market Center. Quote Share Payments will be based in equal proportions on: (a) Average quoted size at or better than NBBO; and (b) average time spent quoting at or better than NBBO. Proposed Rule 5950(c)(2)(B).

The Exchange believes that allocation of MQP Fees to Quote Share Payments and Trade Share Payments properly reflects the efforts of MQP Market Makers to improve the quality, depth, and/or liquidity of these securities (*e.g.,* from initial quotation to final trade and execution). The Exchange believes that the combination of quote and trade payments in the Program is more effective in measuring the participation of an MQP Market Maker and the resulting liquidity that is added to the marketplace. A traditional per share incentive plan (*e.g.,* a make-take pricing model) often is not attractive to market makers in respect of low volume securities because of the risk associated with the liquidity characteristics of the security coupled with the low volume and reduced revenue opportunity; from the perspective of market makers the costs may outweigh the benefit of liquidity provision. Additionally, by including a component dedicated to quote quality, the program provides an incentive to narrow spreads and increase the size at NBBO even when there are few or no trades occurring. As such, the Exchange believes that as MQP Market Makers increase the overall quality of the market it is important to compensate them for both their quote and trade participation in targeted securities.

[61] Proposed Rule 5950(b)(2)(B).

[62] Proposed Rule 5950(b)(2)(C).

[63] Proposed Rule 5950(b)(2)(D).

Market Maker(s) in an MQP Security. Any portion of an MQP Fee that is not credited to eligible MQP Market Makers will be refunded to the MQP Company.[64]

Proposed Rule 5950—MQP Credit to Market Makers

When making a market in an MQP Security, an MQP Market Maker must, in addition to fulfilling the market making obligations per Rule 4613,[65] meet or exceed several market quality requirements on a monthly basis to be eligible for an MQP Credit. First, for at least 25% of the time when quotes can be entered in the Regular Market Session [66] as averaged over the course of a month, an MQP Market Maker must maintain: (a) At least 500 shares of attributable, displayed quotes [67] or orders at the NBBO or better on the bid side of an MQP Security; and (b) at least 500 shares of attributable, displayed quotes or orders at the NBBO or better on the offer side of an MQP Security. And second, for at least 90% of the time when quotes can be entered in the Regular Market Session as averaged over the course of a month, a MQP Market Maker must maintain: (a) At least 2,500 shares of attributable, displayed posted liquidity on the NASDAQ Market Center that are priced no wider than 2% away from the NBBO on the bid side of an MQP Security; and (b) at least 2,500 shares of attributable, displayed posted liquidity on the NASDAQ Market Center that are priced no wider than 2% away from the NBBO on the offer side of an MQP Security.[68]

MQP Credits for each MQP Security will be calculated monthly and credited quarterly on a pro rata basis to one or more eligible MQP Market Makers. Each MQP Credit will be comprised of a Quote Share Payment that is based on Qualified Quotes, and a Trade Share Payment that is based on Qualified Trades.[69] Trade Share Payments will, as discussed, be based upon the total aggregate share amount of Qualified Trades in an MQP Security executed on the NASDAQ Market Center, and Quote Share Payments will be based in equal proportions on: (a) Average quoted size at or better than NBBO; and (b) average time spent quoting at or better than NBBO.[70]

An MQP Credit will be credited quarterly to an MQP Market Maker on a pro rata basis for each month during such quarter that an MQP Market Maker is eligible to receive a credit pursuant to the proposed rule. However, the calculation to establish the eligibility of an MQP Market Maker will be done on a monthly basis. Thus, for example, if during a quarter an MQP Market Maker was eligible to receive a credit for two out of three months, he would receive a quarterly pro rata MQP Credit for those two months.[71]

NASDAQ may limit, on a Program-wide basis, how many MQP Market Makers are permitted to register in an MQP Security, and will provide notification on its Web site of any such limitation. As discussed above, if a limit is established, NASDAQ will allocate available MQP Market Maker registrations in a first-come-first-served fashion based on successful completion of an MPQ [sic] Market Maker application.[72]

Finally, to give the Exchange and the Commission an opportunity to evaluate the impact of the MQP on the quality of markets in MQP Securities, the Exchange is proposing that the MQP will be effective for a one-year pilot period. During the pilot period, the Exchange will submit monthly reports to the Commission about market quality in respect of the MQP. The reports will endeavor to compare, to the extent practicable, securities before and after they are in the MQP and will include information regarding the MQP such as: (1) Rule 605 metrics; [73] (2) volume metrics; (3) number of MQP Market Makers in target securities; (4) spread size; and (5) availability of shares at the NBBO.

The first report will be submitted within sixty days after the MQP becomes operative.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of targeted securities (including ETFs) on the Exchange during all trading sessions, and to detect and deter violations of Exchange rules and applicable federal securities laws. Trading of the targeted MQP Securities through the Exchange will be subject to FINRA's surveillance procedures for derivative products including ETFs.[74] The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members or affiliates of the ISG [75] and from listed MQP Companies and public and non-public

[64] Proposed Rule 5950(b)(2)(E).

[65] Rule 4613 states that market making obligations applicable to NASDAQ members that are registered as Market Makers include, among other things, quotation requirements and obligations as follows: For each security in which a member is registered as a Market Maker, the member shall be willing to buy and sell such security for its own account on a continuous basis during regular market hours and shall enter and maintain a two-sided trading interest (''Two-Sided Obligation'') that is identified to the Exchange as the interest meeting the obligation and is displayed in the Exchange's quotation montage at all times. Interest eligible to be considered as part of a Market Maker's Two-Sided Obligation shall have a displayed quotation size of at least one normal unit of trading (or a larger multiple thereof); provided, however, that a Market Maker may augment its Two-Sided Obligation size to display limit orders priced at the same price as the Two-Sided Obligation. Unless otherwise designated, a ''normal unit of trading'' shall be 100 shares. After an execution against its Two-Sided Obligation, a Market Maker must ensure that additional trading interest exists in the Exchange to satisfy its Two-Sided Obligation either by immediately entering new interest to comply with this obligation to maintain continuous two-sided quotations or by identifying existing interest on the Exchange book that will satisfy this obligation.

[66] The term ''Regular Market Session'' shall have the meaning given in Rule 4120(b)(4)(D). Proposed Rule 5950(e)(8).

[67] These are quotes that are attributable to members and not hidden quotes.

[68] Proposed Rule 5950(c)(1)(B).

For example, regarding the first market quality standard (25%)—in an MQP Security where the NBBO is $25.00 × $25.10, for a minimum of 25% of the time when quotes can be entered in the Regular Market Session as averaged over the course of a month, an MQP Market Maker must maintain bids at or better than $25.00 for at least 500 shares and must maintain offers at or better than $25.10 for at least 500 shares. Thus, if there were 20 trading days in a given month and the MQP Market Maker met this requirement 20% of the time when quotes can be entered in the Regular Market Session for 10 trading sessions and 40% of the time when quotes can be entered in the Regular Market Session for 10 trading sessions then the MQP Market Maker would have met the requirement 30% of the time in that month.

For example, regarding the second market quality standard (90%)—in an MQP Security where the NBBO is $25.00 × $25.10, for a minimum of 90% of the time when quotes can be entered in the Regular Market Session as averaged over the course of a month, an MQP Market Maker must post bids for an aggregate of 2,500 shares between $24.50 and $25.00, and post offers for an aggregate of 2,500 shares between $25.10 and $25.60. Thus, if there were 20 trading days in a given month and the MQP Market Maker met this requirement 88% of the time when quotes can be entered in the Regular Market Session for 10 trading sessions and 98% of the time when quotes can be entered in the Regular Market Session for 10 trading sessions then the MQP Market Maker would have met the requirement 93% of the time in that month.

[69] Proposed Rule 5950(c)(2)(A). This subsection indicates that a Qualified Quote represents attributable and displayed liquidity (either quotes or orders) in an MQP Security; that a quote or order entered by an MQP Market Maker in an MQP Security is only a Qualified Quote if it is posted within 2% of the NBBO; and that a Qualified Trade in an MQP Security represents a liquidity-providing execution of a Qualified Quote on the NASDAQ Market Center.

[70] Proposed Rule 5950(c)(2)(B). *See also supra* note 60.

[71] Proposed Rule 5950(c)(2)(C).

[72] Proposed Rule 5950(c)(3). *See also supra* note 54.

[73] 17 CFR 242.605.

[74] FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[75] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

data sources such as, for example, Bloomberg.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[76] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[77] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers or Companies and other persons using any facility or system which NASDAQ operates or controls, and it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest.

The goal of the MQP—to incentivize members to make high-quality, liquid markets—supports the primary goal of the Act to promote the development of a resilient and efficient national market system. Congress instructed the Commission to pursue this goal by emphasizing multiple policies, including the promotion of price discovery, order interaction, and competition among orders and markets. The MQP promotes all of these policies; it will enhance quote competition, improve NASDAQ liquidity, support the quality of price discovery, promote market transparency and increase competition for listings and trade executions while reducing spreads and transaction costs. Maintaining and increasing liquidity in exchange-listed securities executed on a registered exchange will help raise investors' confidence in the fairness of the market and their transactions. Improving liquidity in this manner is particularly important with respect to ETFs and low-volume securities, as noted by the Joint CFTC/SEC Advisory Commission on Emerging Regulatory Issues.[78]

Each aspect of the MQP adheres to and supports the Act. First, the Program promotes the equitable allocation of fees and dues among issuers. The MQP is completely voluntary in that it will provide an additional means by which issuers may relate to the Exchange without modifying the existing listing options. Issuers can supplement the standard listing fees (which have already been determined to be consistent with the Act) with those of the MQP (which are consistent with the Act as well). While the MQP will result in higher fees for issuers that choose to participate, the issuers receive significant benefits for participating, including committed Market Makers, greater liquidity, and lower transaction costs for their investors. Additionally, issuers will have the ability to withdraw from the Program after an initial commitment in the event they determine that participation is not beneficial. In that case, the withdrawing issuers will automatically revert to the already-approved fee schedule applicable to the market tier in which their shares are listed.

The MQP also represents an equitable allocation of fees and dues among Market Makers. Again, the MQP is completely voluntary with respect to Market Maker participation in that it will provide an additional means by which members may qualify for a credit, without eliminating any of the existing means of qualifying for incentives on the Exchange. Currently, NASDAQ and other exchanges use multiple fee arrangements to incentivize Market Makers to maintain high quality markets or to improve the quality of executions, including various payment for order flow arrangements, liquidity provider credits, and NASDAQ's Investor Support Program (set forth in NASDAQ Rule 7014). Market Makers that choose to undertake increased burdens pursuant to the MQP will be rewarded with increased credits; those that do not undertake such burdens will receive no added benefit. As with issuers, Market Makers that choose to participate in the MQP will be permitted to withdraw from it after an initial commitment if they determine that the burdens imposed by the MQP outweigh the benefits provided.

Additionally, the MQP establishes an equitable allocation of fees among Market Makers that choose to participate and fulfill the obligations imposed by the rule. If one Market Maker fulfills those obligations, the MQP Fee will be distributed to that Market Maker; if multiple Market Makers satisfy the standard, the MQP Fee will be distributed pro rata among them. Any portion of an MQP Fee that is not credited to eligible MQP Market Makers will be refunded to the relevant MQP Company. All fees paid by issuers choosing to participate in the MQP, both initial and supplemental MQP Fees, will be available for distribution to eligible NASDAQ Market Makers. In other words, all of the benefit of the MQP Fees will flow to high-performing Market Makers rather than to NASDAQ, provided that at least one Market Maker fulfills the obligations under the proposed rule.

The MQP is designed to avoid unfair discrimination among Market Makers and issuers. The proposed rule contains objective, measurable (universal) standards that NASDAQ will apply with care. These standards, both for issuers and for Market Makers, will be applied equally to ensure that similarly situated parties are treated similarly. This is equally true for inclusion of issuers and Market Makers, withdrawal of issuers and Market Makers, and termination of eligibility for the MQP. The standards are carefully constructed to protect the rights of all parties wishing to participate in the Program by providing notice of requirements and a description of the selection process. NASDAQ will apply these standards with the same care and experience with which it applies the many similar rules and standards in NASDAQ's rule manuals.

NASDAQ notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, NASDAQ must continually adjust its fees and program offerings to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. NASDAQ believes that all aspects of the proposed rule change reflect this competitive environment because the MQP is designed to increase the credits provided to members that enhance NASDAQ's market quality.

Finally, NASDAQ notes that the proposed paid for market making system has been used successfully for years on NASDAQ OMX Nordic's First North market. The First North paid for market making system has been quite beneficial to market participants including investors and listing companies (issuers) that have experienced market quality and liquidity with narrowed spreads. The Exchange believes that the proposed MQP will similarly enjoy positive results to the benefit of investors in MQP Securities and Companies related to them and the financial markets as a whole.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not

[76] 15 U.S.C. 78f.

[77] 15 U.S.C. 78f(b)(4) and (5).

[78] *See* Recommendations Regarding Regulatory Responses To The Market Events Of May 6, 2010, February 18, 2011 (Recommendation that the SEC evaluate whether incentives or regulations can be developed to encourage persons who engage in market making strategies to regularly provide buy and sell quotations that are "reasonably related to the market."). Available at *http://www.sec.gov/spotlight/sec-cftcjointcommittee/021811-report.pdf.*

necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall:

(a) By order approve or disapprove such proposed rule change; or

(b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. The Commission requests comment, in particular, on the following aspects of the proposed rule change:

1. Much of the reasoning, empirical data, and academic literature discussed by NASDAQ in its proposal is based on providing market making incentives to enhance the market quality of, and capital formation for, smaller operating companies. However, the MQP proposed by NASDAQ would apply only to certain exchange-traded derivative securities products (defined in the proposal as MQP Securities to include Exchange Traded Funds, Linked Securities, and Trust Issued Receipts), and not to operating companies. Are the same arguments and rationale discussed by NASDAQ for operating companies equally applicable to exchange-traded products? Would the reported effects of other market-making incentive programs designed to enhance the market quality of traded operating companies be similar if applied to exchange-traded products? If so, how so? If not, why not?

2. How, if at all, might a market-making incentive program applied to exchange-traded products impact the operating companies that comprise the index underlying such exchange-traded products? Under what circumstances could an impact on those companies be beneficial or harmful? Could any impact differ depending on whether or not an exchange-traded product uses derivatives to gain exposure to such companies, or uses leverage or inverse leverage?

3. What are commenters' views on NASDAQ's assertion that being included as a ''component'' of an exchange-traded product (such as an ETF) results in benefits to an individual operating company? Do commenters agree with this assertion? Why or why not? Could such benefits arise independently from a company's inclusion in an underlying index, regardless of whether an exchange-traded product tracking such an index is traded? Is there any data available that analyzes the impact on a company when it becomes a component of an underlying index versus when it becomes a portfolio component of an exchange-traded product that tracks such an index?

4. How does the rationale in support of trading lesser-known or smaller operating companies translate to the need for similar support of an exchange-traded product that tracks these companies? What about an exchange-traded product that tracks and invests in very liquid companies, but itself has low levels of liquidity? Is there an independent rationale for needing to support these types of exchange-traded products when the market does not? Are there unintended consequences of incentivizing such products? If so, what are they?

5. Given the inherent arbitrage link between trading exchange-traded products and their underlying holdings, why would a lack of liquidity in such a product impact the ability of market makers to quote relatively narrow bids and offers? What, if anything, does a lack of liquidity or wide bid-ask spread in an exchange-traded product indicate about the ability of a market maker to make effective use of arbitrage and the creation/redemption mechanisms often associated with exchange-traded products? How, if at all, would a market-making incentive program affect any intraday premium (discount) of the traded price of an exchange-traded product above (below) its intraday indicative value?

6. NASDAQ states that the MQP is designed to promote market quality in MQP Securities by, among other things, encouraging narrow spreads and greater liquidity. Under the proposal, MQP Market Makers would receive MQP Credits for quoting at or near the NBBO, regardless of the actual NBBO spread. The Commission seeks specific commentary on any potential impact of the proposed rules on the market quality of the MQP Securities. Do commenters agree with the Exchange that the MQP would encourage tighter quoted prices and greater quoted size at the NBBO for MQP Securities? If so, please explain. If not, why not?

7. Do commenters believe that the MQP would result in MQP Market Makers quoting at better prices (and larger sizes) than they would otherwise quote without the incentives provided by the Program? Why or why not?

8. If the market qualities of two securities share similar characteristics (quoted spread, size, volume, etc.) but one is supported by MQP incentives and the other is not, what, if anything, does that suggest about the comparative robustness of those market qualities? Are there aspects of this type of incentivized market quality that should concern investors? Are such apparent improvements in market quality consistent with the Act and investor protection? Why or why not?

9. FINRA Rule 5250 prohibits FINRA members from directly or indirectly accepting payment from an issuer of a security for acting as a market maker. NASDAQ notes in its filing that it expects FINRA to file a proposed rule change to amend its Rule 5250 to exempt NASDAQ programs, such as the MQP, that are approved by the Commission. In addition, NASDAQ has its own rule, substantially similar to FINRA Rule 5250, which prohibits direct or indirect payment by an issuer to a market maker. The Exchange stated that it designed the MQP to meet the goals of market integrity, investor confidence, and clear member standards discussed in the Commission's order approving NASD Rule 2460 (which is now FINRA Rule 5250).[79] Do commenters believe the MQP would or would not raise concerns regarding investor confidence, market integrity, and member standards? For example, NASD Rule 2460 was implemented, in part, to address concerns about issuers paying market makers to improperly influence the price of an issuer's stock.[80] What are commenters' views on

[79] *See* Securities Exchange Act Release No. 38812 (July 3, 1997), 62 FR 37105 (July 10, 1997) (SR–NASD–97–29).

[80] *See id.* at 37107 (''Specifically, the Commission finds that the rule preserves the integrity of the marketplace by ensuring that quotations accurately reflect a broker-dealer's interest in buying or selling a security. The decision by a firm to make a market in a given security and the question of price generally are dependent on a number of factors, including, among others, supply and demand, the firm's expectations toward the market, its current inventory position, and exposure to risk and competition. This decision should not be influenced by payments to the member from issuers or promoters. Public investors expect broker-dealers' quotations to be based on the factors

Continued

whether, and if so, how, the MQP would be consistent with this basis?

10. Could there be conflicts of interest between an MQP Company (the issuer) and the designated MQP Market Maker(s) for such MQP Securities participating in the Program? If so, what are those conflicts of interest? [81] Please explain whether NASDAQ's proposal adequately addresses such potential conflicts.

11. In order to address concerns about potential conflicts of interest between issuers and market makers, NASDAQ stated that it designed the MQP to have clear and precise standards for all parties in the Program (*e.g.,* MQP Companies and MQP Market Makers).[82] Should such participation standards also be objective to ensure that there is a level playing field in determining who the issuers and market makers are for a particular MQP Security in the Program? Are the proposed criteria for participation by potential MQP Market Makers and/or potential MQP Companies in the MQP sufficiently clear, precise, and objective? Why or why not?

12. Is it appropriate and consistent with the Act to allow MQP Companies to pay the additional Supplemental MQP Fee at their discretion? Why or why not? Is it appropriate and consistent with the Act to allow MQP Companies to be able to decide how to allocate their Supplemental MQP Fee between Quote Share Payments and Trade Share Payments? Why or why not? What would be the impact on market maker incentives of allowing MQP Companies to pay the additional Supplemental MQP Fee and to decide how to allocate its Supplement MQP Fee between Quote Share Payments and Trade Share Payments? Please explain.

13. With respect to a series of MQP Securities, should the MQP Company paying the MQP Fee be the sponsor or the fund? What impact, if any, would it have on fund investors if the fund pays the MQP Fee as opposed to the sponsor? Are the proposed Rules sufficiently clear as to which entity will be paying the MQP Fee?

14. Section 11(d)(1) of the Act generally prohibits a firm that is both a broker and a dealer in securities from extending or maintaining any credit on any new issue security if the broker-dealer participated in the distribution of the new issue security within the preceding 30 days. The Commission has granted relief to authorized participants from these restrictions if, among other things, neither the broker-dealer authorized participant, nor any natural person associated with such broker-dealer authorized participant, directly or indirectly, receives from the fund complex any payment, compensation, or other economic incentive to promote or sell the shares of the fund to persons outside the fund complex, other than non-cash compensation permitted under NASD Rule 2380. Should authorized participants participating in the creation and redemption of shares of MQP Securities that are also MQP Market Makers in those same MQP Securities be eligible to receive MQP Credits derived from Trade Share Payments? Would MQP Credits derived from Trade Share Payments give these authorized participants economic incentives to promote or sell shares of the MQP Security? Should such payments be viewed by the Commission as coming directly or indirectly from the fund complex of the MQP Security? Should MQP Credits derived from Trade Share Payments disqualify broker-dealer authorized participants from relying on the Commission's exemption from Section 11(d)(1) of the Act?

15. Could the MQP have an impact (either positive or negative) on incentives for market making in other exchange-traded products listed and traded on NASDAQ that are not eligible for and/or do not participate in the Program, either because NASDAQ has limited the total number of MQP Securities that any one MQP Company may have in the MQP, the MQP Company does not qualify for the MQP, or the MQP Company's application for participation is otherwise denied? If so, what type of impact, and why? If not, why not? Please explain.

16. Proposed Rule 5950(d)(1)(A) states that the MQP will terminate if an MQP Security sustains an average NASDAQ ATV of two million shares or more for three consecutive months. Is this proposed threshold for discontinuance in the Program reasonable? If so, why? If not, why not? Should there be an alternative threshold or measure to determine termination from the Program? Please explain.

17. Could the MQP have unintended consequences on fair and orderly markets in an MQP Security when such security leaves the program? If so, what could these consequences be? If not, why not? Please explain.

18. NASDAQ has proposed to implement the MQP on a one-year pilot basis. Is one-year a reasonable time period during which to assess the impact of the proposed rules? If not, why not? Please explain.

19. What additional data, if any, should be provided by NASDAQ to help assess during the pilot period whether the MQP is achieving its stated goals? For example, if the Exchange required MQP Securities to be listed and traded outside the MQP for a period of time before being eligible for the MQP, could such a requirement provide useful ''before and after'' data for MQP Securities to permit the Exchange and the Commission to more accurately assess the market quality of the securities before participating in the Program and the market quality of the same securities while participating in the Program? If so, how? If not, please explain.

20. The MQP proposed rule provides for certain public disclosures relating to the Program (*i.e.,* notifications on NASDAQ's Web site will include names of the MQP Companies and the MQP Market Makers that are accepted into the Program, how many MQP Securities an MQP Company may have in the Program, the specific names of the MQP Securities that are listed pursuant to the Program, the identity of the MQP Market Makers in each MQP Security, the amount of the supplemental MQP Fee, etc.).[83] Do commenters believe that these disclosures would provide sufficient information to investors? If not, why not? Is there any other information that the Exchange should provide on its Web site regarding the MQP and participating MQP Securities, MQP Companies, and MQP Market Makers? For example, should NASDAQ be required to provide notification on its Web site of any notices from an MQP Company or MQP Market Maker to withdraw from the Program? What

described above. If payments to broker-dealers by promoters and issuers were permitted, investors would not be able to ascertain which quotations in the marketplace are based on actual interest and which quotations are supported by issuers or promoters. This structure would harm investor confidence in the overall integrity of the marketplace. The Commission finds that the proposed rule supports a longstanding policy and position of the NASD and establishes a clear standard of fair practice for member firms.'')

[81] The Commission's order approving NASD Rule 2460 discussed conflicts of interest that may exist between issuers and market makers. *See id.* at 37106 (''It has been a longstanding policy and position of the NASD that a broker-dealer is prohibited from receiving compensation or other payments from an issuer for quoting, making a market in an issuer's securities or for covering the member's out-of-pocket expenses for making a market, or for submitting an application to make a market in an issuer's securities. As stated in Notice to Members 75–16 (February 20, 1975), such payments may be viewed as a conflict of interest since they may influence the member's decision as to whether to quote or make a market in a security and, thereafter, the prices that the member would quote.'')

[82] *See supra* note 44 and accompanying text.

[83] *See* Proposed Rule 5950(a)(1)(C) and (b)(2)(B)(iii).

advantages or disadvantages would such disclosure provide? Please explain.

21. Would it be helpful to investors to have public notice of an MQP Company's participation in the Program through means other than on the Exchange's Web site, such as in the MQP Company's periodic reports to the Commission, on the MQP Company's Web site, or through a ticker symbol identifier on the consolidated tape? Why or why not?

22. What are commenters' views on whether the proposed disclosures are sufficient to enable all investors, even less sophisticated investors, to understand the potential impact of the proposed MQP on the market quality of an MQP Security, including that an MQP Company's participation in the Program is voluntary and subject to withdrawal, or that the MQP Security may become ineligible for the Program if its trading volume reaches sufficiently high levels?

23. Should the Exchange be required to publicly (and anonymously) disclose statistics on the performance of MQP Market Makers? Would such disclosure provide meaningful information to investors (*e.g.,* would such disclosure provide investors the opportunity to assess how much perceived liquidity is being provided by MQP Market Makers, as opposed to liquidity provided by market makers and other market participants who are not paid an MQP Credit)? If so, what information should be disclosed and why? If not, why not? What advantages or disadvantages would such disclosure provide? Please explain.

Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2012–043 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–043. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549–1090, on official business days between 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2012–043 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[84]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8789 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66762; File No. SR–EDGX–2012–12]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Amendments to the EDGX Exchange, Inc. Fee Schedule

April 6, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 30, 2012 the EDGX Exchange, Inc. (the ''Exchange'' or the ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its fees and rebates applicable to Members[3] of the Exchange pursuant to EDGX Rule 15.1(a) and (c). All of the changes described herein are applicable to EDGX Members. The text of the proposed rule change is available on the Exchange's Internet Web site at *http://www.directedge.com,* at the Exchange's principal office, and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a technical amendment to the description of the Mega and Mini Tape B Tiers in footnote 1 to clarify that these rebates ($0.0034 per share and $0.0030 per share, respectively) are provided for liquidity added on EDGX in Tape B Securities only.

Flag E represents a customer internalization[4] charge per side if a Member inadvertently matches with itself. In order to provide additional transparency to Members, Flag E is proposed to be bifurcated into two flags and re-named to state ''Internalization'' instead of ''Customer Internalization'': Flag EA (internalization on the adding liquidity side) and Flag ER (internalization on the removing

[84] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4 .

[3] A Member is any registered broker or dealer, or any person associated with a registered broker or dealer, that has been admitted to membership in the Exchange.

[4] This occurs when two orders presented to the Exchange from the same Member (i.e., MPID) are presented separately and not in a paired manner, but nonetheless inadvertently match with one another. Members are advised to consult Rule 12.2 respecting fictitious trading.

liquidity side). No change is proposed to the standard rate of $0.00035 per share. A conforming amendment is proposed to be made to the first sentence of footnote 11 to make clear that either Flag EA or ER could be yielded for internalization. In addition, the last sentence of footnote 11 on the fee schedule provides that ''if a Member internalizes more than 4% of their ADV on EDGX (added, removed, and routed liquidity) and the Member, at a minimum, meets the criteria for the Mega Tier rebate of $0.0032 per share in footnote 1, then the Member's receives a rebate of $0.00015 per share.'' This tier is proposed to be amended to state that in the latter situation, a Member would receive the applicable rebate in footnote 1 of the fee schedule for adding liquidity or would be charged the applicable removal rate in footnote 1 or 12. This enables the Member to ascertain if they are on the ''adding liquidity side'' or ''removing liquidity side'' for purposes of internalization.

The Exchange proposes to add footnote 13 to its fee schedule to establish a new Investor Tier under which a Member can qualify for a rebate of $0.0030 per share if they meet the following criteria: (i) On a daily basis, measured monthly, posts an ADV of at least 8 million shares on EDGX, where added flags are defined as B, HA, V, Y, MM, 3, or 4 (ii) have an ''added liquidity'' to ''removed liquidity'' ratio of at least 70% where added flags are defined as B, HA, V, Y, MM, 3, or 4 [5] and removal flags are defined as MT, N, W, PI, or 6; and (iii) have a message-to-trade ratio of less than 4:1. The Exchange notes that the message-to-trade ratio is calculated by including total messages as the numerator (orders, cancels, and cancel/replace messages) and dividing it by total executions.[6] The Exchange also notes that any cancel/replace message, regardless of whether it is a partial cancel, is considered a new order.

The Exchange proposes to amend the description of Flag K in reference to orders routed to the PSX to include the ROUE [7] routing strategy in addition to the ROUC routing strategy. The Exchange proposes to continue to assess a charge of $0.0025 per share.

Similarly, the Exchange proposes to amend the description of Flag BY in reference to orders routed to the BATS BYX Exchange to include the ROUE routing strategy in addition to the ROUC and ROBY routing strategies. The Exchange proposes to continue to offer a rebate of $0.0002 per share.

The Exchange proposes to make technical amendments to the fee schedule to: (i) substitute the phrase ''are defined as'' for ''include'' in footnote 12; (ii) replace Flag H with Flag HA in footnote 12 since Flag HA replaced Flag H effective March 1, 2012; [8] and (iii) remove the word ''customer'' in the description of Flags 5 and footnote 11 so that it now would read ''Internalization.''

The Exchange proposes to implement these amendments to its fee schedule on April 1, 2012.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with the objectives of Section 6 of the Act,[9] in general, and furthers the objectives of Section 6(b)(4),[10] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

The Exchange believes that the proposed technical amendment to the Mini and Mega Tape B Tiers adds additional transparency to its fee schedule for investors as it clarifies that the tiered rate is only applicable as to Tape B securities. The Exchange believes that the proposed technical amendment to delete Flag E and replace it with Flags EA and ER promotes market transparency and improves investor protection by adding additional transparency to its fee schedule by more precisely delineating for Members whether they are ''adders of liquidity'' or ''removers of liquidity'' for purposes of paying the internalization fee. The Exchange also believes that the proposal is non-discriminatory because it applies to all Members.

Finally, the internalization rebate is equitable in that it is in line with the EDGX fee structure [11] which currently has a maker/taker spread of $0.0006 per share (the standard rebate to add liquidity on EDGX is $0.0023 per share, while the standard fee to remove liquidity is $0.0029 per share). EDGX also has a variety of tiered rebates ranging from $0.0023–$0.0034 per share, which makes its maker/taker spreads range from $.0006 (standard add—standard removal rate), –$.0001 (standard removal rate—Super Tier rebate), –$0.0002 (standard removal rate—Ultra Tier rebate), –$0.0003 (standard removal rate—Mega Tier rebate of $0.0032), and –$.0005 (standard removal rate—Mega Tier rebate of $0.0034 per share). As a result of the internalization rebate, Members who internalized and met the criteria to satisfy the Mega Tier and the volume threshold of 4% of their ADV on EDGX would be rebated $0.00032 per share per side of an execution (the applicable rebate in footnote 1 for adding liquidity) and be charged $0.0029 per share per side (the applicable removal rate in footnote 1, in this case). This makes the total net rebate equal $0.0003 per share, which would be an internalization rate that is no more favorable than the prevailing maker/taker spread by satisfying the Mega Tier rebate of $0.0032 ($–0.0003).

The Exchange believes that the Investor Tier is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities as it rewards Members with order flow characteristics that contribute meaningfully to price discovery on the Exchange. In other words, Members that primarily post liquidity and provide longer duration orders are more valuable Members to the Exchange and the marketplace in terms of liquidity provision. The EDGX Investor Tier also encourages Members to primarily add liquidity in order to satisfy the ''added liquidity'' to ''removed liquidity'' ratio of at least 70%. Such increased volume increases potential revenue to the Exchange, and would allow the Exchange to spread its administrative and infrastructure costs over a greater number of shares, leading to lower per share costs. These lower per share costs would allow the Exchange to pass on the savings to Members in the form of higher rebates. The increased liquidity also benefits all investors by deepening EDGX's liquidity pool, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. Volume-based rebates such as the ones proposed herein have been

[5] The Exchange notes that the vast majority of posted liquidity is displayed liquidity (Flags B, V, Y, 3, or 4) and the volume posted from hidden liquidity (Flags HA and MM) is incidental.

[6] The Exchange notes that it counts only the first partial or complete execution resulting from an order if it is filled in parts. So, if a 1,000 share order results in three partial executions of 400 shares, 300 shares, and 300 shares, it counts only the first execution of 400 shares toward the denominator. Thus, the Exchange counts all fills against an order as one trade for purposes of ''total executions.''

[7] *See* Exchange Rule 11.9(b)(3).

[8] *See* Securities Exchange Act Release No. 66558 (March 9, 2012), 77 FR 15432 (March 15, 2012) (SR–EDGX–2012–06).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(4).

[11] In SR–EDGX–2011–13 (April 29, 2011), the Exchange represented that it ''will work promptly to ensure that the internalization fee is no more favorable than each prevailing maker/taker spread.''

widely adopted in the cash equities markets, and are equitable because they are open to all Members on an equal basis and provide discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and introduction of higher volumes of orders into the price and volume discovery processes.

In addition, the rebate is also reasonable in that other exchanges likewise employ similar pricing mechanisms. For example, NASDAQ [12] and NYSE Arca [13] offer investor support programs and investor tiers, respectively. Such programs reward liquidity provision attributes, encourage price discovery and market transparency by encouraging growth in liquidity over a defined baseline, and encourage a low cancellation rate on liquidity-providing orders. EDGX's Investor Tier is similar to NASDAQ's/ NYSE Arca's programs in they both encourage efficient liquidity provision. It is similar to NASDAQ's Investor Support Program in that for NASDAQ members to qualify, among a firm's liquidity-providing orders, it must maintain a ratio of ''orders'' to ''orders executed'' of less than ten to one (i.e., at least one out of every ten liquidity-providing orders submitted must be executed rather than cancelled). Similarly, NYSE Arca's investor tiers require its members to maintain a ratio of cancelled orders to total orders of less than 30% and maintain a ratio of executed liquidity adding volume to total volume of greater than 80%, among other criteria. EDGX's Investor Tier is similar to NYSE Arca's investor tiers in that like NYSE Arca's investor tiers, the Exchange's goal is to incentivize Members to maintain low cancellation rates and provide liquidity that supports the quality of price discovery and promotes market transparency. In addition, similar to the investor tiers of NYSE Arca, EDGX's Investor Tier ''reward[s] providers whose orders stay on the [b]ook and do not rapidly cancel a large portion of their orders placed, which makes the price discovery process more efficient and results in higher fill rates, greater depth and lower volatility. It serves to encourage Members to post orders that are more likely to be executed.'' [14]

The Exchange proposes to amend the description of Flag K in reference to orders routed to the PSX to include the ROUE routing strategy in addition to the ROUC routing strategy. The Exchange proposes to continue to assess a charge of $0.0025 per share. The Exchange believes that by including the ROUE routing strategy in the description of Flag K, the Exchange is providing additional transparency to the fee schedule by broadening that flag's applicability to several routing strategies. This encourages Members to utilize the Exchange to route to various destinations, which results in a lower overall routed rate for Members and allows the Exchange to pass on the savings it receives to the Exchange's Members. The Exchange believes that the proposed rebate is non-discriminatory in that it applies uniformly to all Members.

Similarly, the Exchange proposes to amend the description of Flag BY in reference to orders routed to the BATS BYX Exchange to include the ROUE routing strategy in addition to the ROUC and ROBY routing strategies. The Exchange proposes to continue to offer a rebate of $0.0002 per share. The Exchange believes that by including the ROUE routing strategy in the description of Flag BY the Exchange is providing additional transparency to the fee schedule by broadening that flag's applicability to several routing strategies. This encourages Members to utilize the Exchange to route to various destinations, which results in a lower overall routed rate for Members and allows the Exchange to pass on the savings it receives to the Exchange's Members. The Exchange believes that the proposed rebate is non-discriminatory in that it applies uniformly to all Members.

The Exchange also notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act [15] and Rule 19b–4(f)(2) [16] thereunder. At any time within 60 days of the filing of such proposed rule

[12] *See* NASDAQ Rule 7014. Similarly, NASDAQ established an Investor Support Program (''ISP'') targeting retail and institutional investor orders where firms receive a higher rebate if they meet all of the following criteria: 1) Add at least 10 million shares of liquidity per day via ISP-designated ports; 2) Maintain a ratio of orders-to-orders executed of less than 10 to 1 (counting only liquidity-providing orders and excluding certain order types) on ISP-designated ports; 3) Exceed the firm's August 2010/ 2011 ''baseline'' volume of liquidity added across all the firm's ports. For a detailed description of the Investor Support Program as originally implemented, *see* Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness) (the ''ISP Filing''). *See also* Securities Exchange Act Release Nos. 63414 (December 2, 2010), 75 FR 76505 (December 8, 2010) (NASDAQ–2010–153) (notice of filing and immediate effectiveness); 63628 (January 3, 2011), 76 FR 1201 (January 7, 2011) (NASDAQ–2010–154) (notice of filing and immediate effectiveness); 63891 (February 11, 2011), 76 FR 9384 (February 17, 2011) (NASDAQ–2011–022) (notice of filing and immediate effectiveness); and 64050 (March 8, 2011), 76 FR 13694 March 14, 2011) (SR–NASDAQ–2011–034). *See also* Securities Exchange Act Release No. 65717 (November 9, 2011), 76 FR 70784 (November 15, 2011) (SR–NASDAQ–2011–150).

[13] NYSE Arca also implemented investor tiers where they allow Members to earn a credit of $0.0032 per share for executed orders that provide liquidity to the Book for Tape A, Tape B and Tape C securities when they meet all of the following criteria on a monthly basis: 1) Maintain a ratio of cancelled orders to total orders of less than 30%; 2) Maintain a ratio of executed liquidity adding volume to total volume of greater than 80%; and 3) Firms must add liquidity that represents 0.45% or more of the total U.S. average daily consolidated share volume (''ADV'') per month (volume on days when the market closes early is excluded from the calculation of ADV). *See* Securities Exchange Act Release No. 64593 (June 3, 2011), 76 FR 33380 (June 8, 2011) (SR–NYSEArca–2011–34); Securities Exchange Act Release No. 66115 (January 6, 2012), 77 FR 1969 (January 12, 2012) (SR–NYSEArca–2011–101) (notice of filing and immediate effectiveness of a proposed rule change replacing numerical thresholds with percentage thresholds for the Investor Tiers' volume requirements). *See also* Securities Exchange Act Release No. 66378 (February 10, 2012), 77 FR 9278 (February 16, 2012) (SR–NYSEArca–2012–13).

[14] *See* Securities Exchange Act Release No. 64593 (June 3, 2011), 76 FR 33380 (June 8, 2011) (SR–NYSEArca–2011–34).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 19b–4(f)(2) [sic].

change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–EDGX–2012–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2012–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2012–12 and should be submitted on or before May 3, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–8786 Filed 4–11–12; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of Reporting Requirements Submitted for OMB Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before May 14, 2012. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''Notice of Award and Grant/Cooperative Agreement and Cost Sharing Proposal''.

Frequency: On Occasion.

SBA Form Number's: SBA Forms 1222 and 1224.

Description of Respondents: Grantee's.

Responses: 2,568.

Annual Burden: 205,440.

Curtis Rich,

Acting Chief, Administrative Information Branch.

[FR Doc. 2012–8745 Filed 4–11–12; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

Interagency Task Force on Veterans Small Business Development

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Interagency Task Force meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the fourth public meeting of the Interagency Task Force on Veterans Small Business Development. The meeting will be open to the public.

DATES: Friday, April 27, 2012, from 9 a.m. to 12 noon in the Eisenhower Conference Room, Side A & B, located on the 2nd floor.

ADDRESSES: U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development. The Task Force is established pursuant to Executive Order 13540 and focused on coordinating the efforts of Federal agencies to improve capital, business development opportunities, and pre-established Federal contracting goals for small business concerns owned and controlled by veterans (VOBs) and service-disabled veterans (SDVOSBs). Moreover, the Task Force shall coordinate administrative and regulatory activities and develop proposals relating to ''six focus areas'': (1) Access to capital (loans, surety bonding, and franchising); (2) Ensure achievement of pre-established contracting goals, including mentor protégé and matching with contracting opportunities; (3) Increase the integrity of certifications of status as a small business; (4) Reducing paperwork and administrative burdens in accessing business development and entrepreneurship opportunities; (5) Increasing and improving training and counseling services; and (6) Making other improvements to support veteran's business development by the Federal Government. On November 1, 2011, the

Interagency Task Force on Veterans Small Business Development submitted its first report to the President, which included 18 recommendations that were applicable to the ''six focus areas'' identified above. The purpose of the meeting is scheduled as a full Task Force meeting. The agenda will include a status update of recommendations presented in the November 1, 2011 Task Force Report to the President.

In addition, the Task Force will allow time to obtain public comment from individuals and representatives of organizations regarding the areas of focus.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Task Force must contact Raymond B. Snyder, by April 23, 2012, by email in order to be placed on the agenda. Comments for the Record should be applicable to the ''six focus areas'' of the Task Force and emailed prior to the meeting for inclusion in the public record; verbal presentations, however, will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Raymond B. Snyder, Deputy Associate Administrator, Office of Veterans Business Development, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416, at the email address for the Task Force, *vetstaskforce@sba.gov*.

Additionally, if you need accommodations because of a disability or require additional information, please contact Raymond B. Snyder, Designated Federal Official for the Task Force at (202) 205–6773; or by email at: *raymond.snyder@sba.gov,* SBA, Office of Veterans Business Development, 409 3rd Street SW., Washington, DC 20416. For more information, please visit our Web site at *www.sba.gov/vets*.

Dated: April 2, 2012.

Dan Jones,

SBA Committee Management Officer.

[FR Doc. 2012–8751 Filed 4–11–12; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

National Small Business Development Center Advisory Board

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal Advisory Committee meetings.

SUMMARY: The SBA is issuing this notice to announce the location, date, time and agenda for the third quarter meetings of the National Small Business Development Center (SBDC) Advisory Board.

DATES: The meetings for the 3rd quarter will be held on the following dates: Tuesday, April 17, 2012 at 1:00pm EST, Tuesday, May 15, 2012 at 1:00pm EST, Tuesday, June 19, 2012 at 1:00pm EST.

ADDRESSES: These meetings will be held via conference call.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), SBA announces the meetings of the National SBDC Advisory Board. This Board provides advice and counsel to the SBA Administrator and Associate Administrator for Small Business Development Centers.

The purpose of these meetings is to discuss following issues pertaining to the SBDC Advisory Board:

—SBA Update.
—Regional Meetings.
—Board Assignments.
—Member Roundtable.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public however advance notice of attendance is requested. Anyone wishing to be a listening participant must contact Alanna Falcone by fax or email. Her contact information is Alanna Falcone, Program Analyst, 409 Third Street SW., Washington, DC 20416, Phone, 202–619–1612, Fax 202–481–0134, email, *alanna.falcone@sba.gov.*

Additionally, if you need accommodations because of a disability or require additional information, please contact Alanna Falcone at the information above.

Dan S. Jones,

Committee Management Officer.

[FR Doc. 2012–8749 Filed 4–11–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 7607]

Shipping Coordinating Committee; Notice of Committee Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 1 p.m. on Thursday, June 14, 2012, in Room 5–1224 of the United States Coast Guard Headquarters Building, 2100 Second Street SW., Washington, DC 20593–0001. The primary purpose of the meeting is to prepare for the fifty-fifth Session of the International Maritime Organization's (IMO's) Subcommittee on Stability and Load Lines and on Fishing Vessels Safety (SLF) to be held at the IMO Headquarters, United Kingdom, February 18–22, 2013.

The matters to be discussed on the agenda include:

—Adoption of the agenda
—Decisions of other IMO bodies
—Development of second generation intact stability criteria
—Development of guidelines on safe return to port for passenger ships
—Development of guidelines for verification of damage stability requirements for tankers
—Review of the damage stability regulations for ro-ro passenger ships
—Revision of SOLAS chapter II–1 subdivision and damage stability regulations
—Development of provisions to ensure the integrity and uniform implementation of the 1969 TM Convention
—Development of amendments to part B of the 2008 IS Code on towing and anchor handling operations
—Consideration of IACS unified interpretations
—Development of amendments to the criterion for maximum angle of heel in turns of the 2008 IS Code
—Biennial agenda and provisional agenda for SLF 56
—Election of Chairman and Vice-Chairman for 2014
—Any other business
—Report to the Maritime Safety Committee

Members of the public may attend this meeting up to the seating capacity of the room. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LCDR Catherine Phillips, by email at *Catherine.A.Phillips@uscg.mil,* by phone at (202) 372–1374, by fax at (202) 372–1925, or in writing at Commandant (CG–5212), U.S. Coast Guard, 2100 2nd Street SW., Stop 7126, Washington, DC 20593–7126 not later than June 7, 2012, 7 days prior to the meeting. Requests made after June 7, 2012 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Headquarters building. The Headquarters building is accessible by taxi and privately owned conveyance (public transportation is not generally available). However, parking in the vicinity of the building is extremely limited. Additional information regarding this and other IMO SHC public meetings may be found at: *www.uscg.mil/imo.*

Dated: April 6, 2012.

Brian Robinson,

Executive Secretary, Shipping Coordinating Committee, Department of State.

[FR Doc. 2012–8830 Filed 4–11–12; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2012–0033]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by June 11, 2012.

ADDRESSES: You may submit comments identified by DOT Docket ID 2012–0033 by any of the following methods:

Web Site: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Ferroni, 202–366–9237, Office of Natural Environment, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Possible Inclusion of Specific Pavement Types in the FHWA Traffic Noise Model: Regulatory and Procedural Changes.

Background: The Federal Highway Administration (FHWA) has been actively involved in what today the highway noise industry refers to as ''quieter pavements.'' In 2003, the FHWA entered into the Quiet Pavement Pilot Program with the Arizona Department of Transportation, co-sponsored the 2004 International Scan on ''Quieter Pavement Systems in Europe,'' and funded several national workshops, trainings and informational outreach pieces on this topic. In 2005, the FHWA began funding the ''Pavement Effects Implementation Study'' (PEI) to see how more specific pavement types could be incorporated into the FHWA Traffic Noise Model (FHWA TNM). The incorporation of specific pavement types into TNM would require State Departments of Transportation to use these more specific pavement types in TNM and would result in additional regulatory and procedural changes.

The PEI currently is out of funding but an interim report will soon be released. Before additional time, effort and funding are put into completing the PEI, it is important to conduct a user-need analysis to determine whether our stakeholders, primarily State Departments of Transportation, still want us to complete this research, knowing that it would result in regulatory and procedural changes. The information would cover the topics of being required to use a more specific pavement type(s), being required to maintain the specific pavement type selected, and being required to call a project, a Type I project, if the original pavement is replaced or overlaid with a louder pavement.

Respondents: Approximately 60 entities.

Frequency: Once.

Estimated Average Burden per Response: Approximately 30 minutes.

Estimated Total Annual Burden Hours: Approximately 30 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: April 2, 2012.

Juli Huynh,

Chief, Management Programs and Analysis Division.

[FR Doc. 2012–8847 Filed 4–11–12; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0091]

Notice of Fiscal Year 2012 Cooperative Agreement Solicitation for Applications; Specialized Heavy Vehicle Inspection (SHVI) Study

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; request for applications.

SUMMARY: This notice is to inform the public of a FY 2012 cooperative agreement opportunity being offered by the FMCSA in cooperation with the Federal Highway Administration (FHWA) to State agencies responsible for large truck roadside safety inspections. The FMCSA announces this cooperative agreement opportunity based on authorities provided for in the Safe, Accountable, Flexible, Efficient, Transportation Equity Act: A Legacy of Users (Pub. L. 109–59). The cooperative agreement opportunity is to support the FMCSA and the FHWA to collect data for a Specialized Heavy Vehicle Inspection (SHVI) Study.

DATES: Applications are due by May 4, 2012.

FOR FURTHER INFORMATION CONTACT: Please contact the following FMCSA staff with questions or information on this cooperative agreement opportunity: Luke Loy, *luke.loy@dot.gov,* 202–366–0676. FMCSA staff may be reached at 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 9 a.m. to 5 p.m., EST, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background and Purpose

In an effort to better understand the safety performance of heavier vehicles, the FMCSA and the FHWA are partnering to implement the Specialized Heavy Vehicle Inspection (SHVI) Study Cooperative Agreement. The SHVI Study Cooperative Agreement will provide funding to State agencies responsible for large truck roadside safety inspections. The purpose of the

Study is to collect safety data from roadside inspections on vehicles exceeding certain weight levels to determine if there are any associations between higher vehicle weights and motor carrier safety violations, particularly those with out-of-service conditions.

Detailed information on applicant expectations and the application process for these cooperative agreements will be provided in a Notice of Funding Availability to be released April 16, 2012 or soon thereafter. The FMCSA intends to enter into these cooperative agreements by June 1, 2012 or as soon thereafter as administratively practicable.

The FMCSA uses the standard grant application form and quarterly reporting process. The FMCSA requires the Standard Form 424 (Application for Federal Assistance). Applicants for this cooperative agreement will be expected to also complete a Project Narrative and Budget Narrative to support their application. FMCSA uses GrantSolutions, a grants management information technology system, to provide all cooperative agreement documents electronically to its financial processing office. GrantSolutions is a comprehensive grants management system provided by the Grants Center of Excellence (COE). The Grants COE serves as one of three consortia leads under the Grants Management Line of Business E-Gov initiative offering government-wide grants management system support services. Electronic signature of grant documents in GrantSolutions is the Agency's preferred method for executing grant agreement. Additional information will be provided to grantees during the grant award process. Grantees will, however, be required to submit the completed Automated Clearing House (ACH) Vendor Payment Form (SF–3881) directly to FMCSA's financial processing office by U.S. Postal Service, courier service or secure fax. All SHVI Study cooperative agreement applications must be submitted electronically through Grants.gov.

Application Information for FY 2012 Grants

Eligible Entities: State agencies with the responsibility to conduct large truck roadside safety inspections.

Evaluation Factors: The following evaluation factors will be used in reviewing the applications for all FMCSA discretionary grants:

(1) Prior performance—Completion of identified programs and goals per the project plan.

(2) Effective Use of Prior Grants—Demonstrated timely use and expensing of available funds.

(3) Ability of the applicant to support the strategies and activities in the proposal for the entire project period of performance.

(4) Use of innovative approaches in executing a project plan to address identified safety issues.

(5) Feasibility of overall program coordination and implementation based upon the project plan.

Application Due Date: May 4, 2012.

Applications submitted after due dates may be considered on a case-by-case basis and are subject to availability of funds.

Issued on: April 5, 2012.

Kelly Leone,

Associate Administrator, Research and Information Technology.

[FR Doc. 2012–8772 Filed 4–11–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0324]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt eleven individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective April 12, 2012. The exemptions expire on April 12, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

Background

On February 13, 2012, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (77 FR 7657). That notice listed eleven applicants' case histories. The eleven individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the eleven applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The eleven exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, retinal detachment, reduced vision, prosthesis, macular scar, pituitary tumor and esotropia. In most cases, their eye conditions were not recently developed. Seven of the applicants were either born with their vision impairments or have had them since childhood. The four individuals sustained their vision conditions as adults and have had them for a period of 18 to 30 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these eleven drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 4 to 52 years. In the past 3 years, none of the drivers were involved in crashes, and one of the drivers was convicted of a moving violation in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the February 13, 2012 notice (77 FR 7657).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the eleven applicants, none of the drivers were involved in crashes and one of the drivers was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the eleven applicants listed in the notice of February 13, 2012 (77 FR 7657).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the eleven individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received one comment in this proceeding. The Pennsylvania Department of Transportation is in favor of granting Federal vision exemptions to Daniel I. Miller and Roger L. Courson.

Conclusion

Based upon its evaluation of the eleven exemption applications, FMCSA exempts John E. Chitty (FL), Roger L. Courson (PA), Revis D. Durbin (IL), James D. Evans (MD), Lowell S. Johnson (MN), Chet A. Keen (UT), Julian A. Mancha (TX), Daniel I. Miller (PA), Elijah Mitchell (TX), Gregory M. Quilling (VA), and Donald L. Schaeffer (MO) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: April 3, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–8775 Filed 4–11–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FTA Section 5307 Urbanized Area Formula Program: Allocation of Funding Caps for Treating Fuel and Electric Utility Costs for Vehicle Propulsion as a Capital Maintenance Expense

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The Consolidated and Further Continuing Appropriations Act, 2012 (Pub. L. 112–055) permits the Federal Transit Administration (FTA) to treat fuel costs for vehicle operations, including utility costs for the propulsion of electrical vehicles, as a capital maintenance item for grants made in FY 2012 under the Urbanized Area Formula Program, up to a total of $100,000,000. FTA announced this provision and its implementation in the *FTA Fiscal Year 2012 Notice of Apportionments, Allocations, and Program Information,* published in the **Federal Register** on January 11, 2012 (Vol. 77, No. 7 1786–1856). Since total obligations for this purpose are limited to $100,000,000, FTA is limiting the use of funds for this purpose to program recipients that responded to an announcement which was posted at *www.grants.gov* on January 25 and closed on February 29. Based on the $100,000,000 cap on use of this provision, FTA has allocated funding caps to program recipients that responded to this announcement based on their relative share of the FY 2012 Section 5307/5340 formula apportionment. Recipients are advised that this provision does not provide any funding in addition to their Section 5307/5340 program apportionment.

FOR FURTHER INFORMATION CONTACT: For general information about this notice contact David Schneider, Acting Director, Office of Transit Programs, at (202) 493–0175. Please contact the appropriate FTA regional office for any specific requests for information or technical assistance.

SUPPLEMENTARY INFORMATION: The Consolidated and Further Continuing Appropriations Act, 2012, permits FTA to treat fuel costs for vehicle operations, including utility costs for the propulsion of electrical vehicles, as a capital maintenance item for grants made in FY 2012 under the Urbanized Area Formula Program, up to a total of $100,000,000. FTA announced this provision and its implementation in the *FTA Fiscal Year 2012 Notice of Apportionments, Allocations, and Program Information,* published in the **Federal Register** on January 11, 2012 (Vol. 77, No. 7 1786–1856). Program recipients in the identified urbanized areas are eligible for reimbursement of fuel and electrical utility costs for vehicle propulsion under this provision at an 80/20 Federal/local share.

Since total obligations for this purpose are limited to $100,000,000, the use of funds for this purpose is limited to urbanized areas that responded to the solicitation that was announced in the January 11, 2012 *FTA Fiscal Year 2012 Notice of Apportionments, Allocations, and Program Information.* Applications were received between January 25 and February 29 via *www.grants.gov.*

Eligible respondents were required to be either the designated recipient of Section 5307 formula apportionments in urbanized areas over 200,000 in population or a State Department of Transportation or other designee for urbanized areas under 200,000 in population. FTA received requests from 70 large UZAs and 24 States, on behalf of 106 small UZAs. The total amount requested was $237,168,845. To allocate the available resources, FTA has determined funding caps for all requesting UZAs and States (see Table 1 and 2) proportional to the Section 5307/5340 formula apportionment. Where a UZA or State requested less than the calculated cap amount, the funding reflects the requested amount. Table 1 includes the name of each requesting urbanized area over 200,000 in population, the name of the requesting designated recipient(s), and the dollar cap on reimbursements for all funding recipients within the urbanized area. Table 2 shows the States that requested this provision, the list of small urbanized areas for which the State submitted requests, and the statewide funding cap on reimbursements made through each State's Governor's apportionment. Although there may be additional small urbanized areas within the states listed in Table 2, the funds displayed in Table 2 can only be used for the specific small urbanized areas listed, as these areas were identified by the States in their requests to take advantage of the fuel/electric propulsion provision. The State may sub-allocate the funding cap among the listed small urbanized areas on the basis of need.

Program recipients are advised that the distribution of this provision within an urbanized area is subject to Federal planning requirements and will require coordination between the designated recipient(s), the Metropolitan Planning Organization (MPO), and other direct recipients of FTA funds. Funds sub-allocated to direct recipients within a UZA will be included in their FTA grants. Procurements to which these 5307 funds are applied must comply with Federal procurement requirements and include all applicable Federal procurement clauses.

Recipients are reminded that this provision does not provide any additional funding but rather how they may use a portion of their UZA's Section 5307/5340 program apportionment. Funds granted under this provision will be treated as an alternative use of the eligible recipient's formula funding. While this provision applies to grants made during FY 2012, it is not limited to grants made using FY 2012 apportioned funds and may also include grants made during FY 2012 that include prior year funds. Recipients within the identified urbanized areas are required to obligate funds no later than September 30, 2012. Once funds are obligated, they will remain available until expended, and may be used for eligible costs incurred during the applicant's current fiscal year plus one additional year. FTA does not plan to reallocate funding caps under this provision.

Issued in Washington, DC, this 9th day of April, 2012.

Peter Rogoff,

Administrator.

BILLING CODE P

TABLE 1 - SECTION 5307 FUEL AS CAPITAL MAINTENANCE PROVISION
REIMBURSEMENT LIMITS FOR LARGE URBANIZED AREAS (200,000 OR MORE IN POPULATION)

Large Urbanized Area	Designated Recipient	Program Cap
Albuquerque, NM	City of Albuquerque, NM	$1,386,035
Antioch, CA	Metropolitan Transportation Commission	278,564
Asheville, NC	City of Asheville, NC	175,182
Atlanta, GA	MARTA	6,369,096
Augusta-Richmond County, GA--SC	City of Augusta	222,669
Barnstable Town, MA	Cape Cod Regional Transit Authority	520,021
Boise City, ID	Valley Regional Transit	251,949
Canton, OH	Stark Area Regional Transit Authority	321,746
Chattanooga, TN--GA	Chattanooga Area RTA	200,000
Chicago, IL--IN	Gary Public Transit Corp & Northwestern Indiana RPC	2,130,100
Cincinnati, OH--KY--IN	Butler County Regional Transit Authority	480,000
Cleveland, OH	Greater Cleveland Regional Transit Authority	1,000,000
Colorado Springs, CO	City of Colorado Springs	538,320
Columbia, SC	Central Midlands Regional Transit Authority	348,379
Columbus, GA--AL	Columbus Consolidated Government	200,341
Dallas--Fort Worth--Arlington, TX	North Central Texas Council of Governments	659,604
Davenport, IA--IL	City of Davenport	140,000
Dayton, OH	Greater Dayton Regional Transit Authority	1,287,847
Denton--Lewisville, TX	Denton County Transportation Authority	299,579
Denver--Aurora, CO	Regional Transportation District	4,397,070
Detroit, MI	SMART & City of Detroit DOT	4,059,087
Eugene, OR	Lane Transit District	511,072
Fayetteville, NC	City of Fayetteville	217,283
Flint, MI	Mass Transportation Authority	150,000
Fort Collins, CO	City of Fort Collins	240,978
Fort Wayne, IN	Fort Wayne Public Transportation Corporation/Citilink	268,873
Fresno, CA	City of Fresno	879,952
Greenville, SC	Greenville Transit Authority	194,589
Gulfport--Biloxi, MS	MS Coast Transit Authority	212,091
Houston, TX	Metropolitan Transit Authority of Harris County, Texas	2,040,376
Huntsville, AL	City of Huntsville	166,737
Indio--Cathedral City--Palm Springs, CA	Southern California Association of Govenments	351,459
Jackson, MS	City of Jackson	230,023
Lancaster--Palmdale, CA	Antelope Valley Transity Authority	784,754
Las Vegas, NV	Regional Transportation Commission of Southern NV	680,663
Los Angeles--Long Beach--Santa Ana, CA	Southern California Association of Govenments	9,568,261
McAllen, TX	Lower Rio Grande Valley Development Council	325,102
Miami, FL	Palm Beach County	5,000,000
Mobile, AL	City of Mobile, AL	277,988
New Orleans, LA	Regional Transit Authority & Regional Planning Comm.	1,249,301
New York--Newark, NY--NJ--CT	County of Rockland, NY	1,075,000
Ogden--Layton, UT	Utah Transit Authority	920,184
Omaha, NE--IA	Transit Authority of the City of Omaha	690,487
Orlando, FL	Central Florida Regional Transportation Authority	1,000,000
Pensacola, FL--AL	Escambia County Board of County Commisioners	267,603
Philadelphia, PA--NJ--DE--MD	Maryland Transit Authority	190,000
Port St. Lucie, FL	St. Lucie County Board of County Commissioners	214,163
Poughkeepsie--Newburgh, NY	Dutchess County, NY	1,645,104
Providence, RI--MA	Rhode Island Public Transit Authority	1,350,000
Provo--Orem, UT	Utah Transit Authority	448,901
Riverside--San Bernardino, CA	Southern California Association of Govenments	2,615,397

TABLE 1 - SECTION 5307 FUEL AS CAPITAL MAINTENANCE PROVISION REIMBURSEMENT LIMITS FOR LARGE URBANIZED AREAS (200,000 OR MORE IN POPULATION)

Large Urbanized Area	Designated Recipient	Program Cap
Sacramento, CA	Sacramento Regional Transit District	**2,041,898**
Salem, OR	Salem Area Mass Transit District	**458,519**
Salt Lake City, UT	Utah Transit Authority	**2,416,934**
San Diego, CA	San Diego Association of Governments	**2,959,280**
San Francisco--Oakland, CA	Metropolitan Transportation Commission	**3,346,604**
San Juan, PR	Puerto Rico Highway & Transportation Auth	**632,933**
Santa Rosa, CA	Metropolitan Transportation Commission	**409,670**
Sarasota--Bradenton, FL	Manatee County Board of County Commissioners	**665,619**
Scranton, PA	County of Lackawanna Transit System	**46,500**
South Bend, IN--MI	South Bend Public Transportation Corporation	**176,000**
Springfield, MA--CT	Pioneer Valley Transit Authority	**1,132,384**
Stockton, CA	San Joaquin Regional Transit District	**672,690**
Tampa--St. Petersburg, FL	Hillsborough Area Regional Transit Authority	**2,276,364**
Toledo, OH--MI	Toledo Area Regional Transit Authority	**500,000**
Tulsa, OK	Metropolitan Tulsa Transit Authority	**400,000**
Washington, DC--VA--MD	Maryland Transit Authority	**10,750,000**
Wichita, KS	City of Wichita	**200,000**
Worcester, MA--CT	Worcester Regional Transit Authority	**812,719**
Youngstown, OH--PA	Western Reserve Transit Authority	**385,758**
Total - Large Urbanized Areas	---	**$89,315,802**

TABLE 2 - SECTION 5307 FUEL AS CAPITAL MAINTENANCE PROVISION
STATEWIDE CAPS FOR SMALL URBANIZED AREAS (UNDER 200,000 IN POPULATION)

State / Small Urbanized Area	Program Cap	State / Small Urbanized Area	Program Cap
Arkansas	**$516,552**	**Kentucky**	**$208,259**
Fayetteville--Springdale, AR		Owensboro, KY	
AR:Fort Smith, AR--OK		Huntington, WV--KY--OH	
Hot Springs, AR		Radcliff--Elizabethtown, KY	
Jonesboro, AR		**Louisiana**	**$406,051**
Pine Bluff, AR		Houma, LA	
Texarkana, TX--Texarkana, AR		Monroe, LA	
California	**$651,782**	Lake Charles, LA	
Manteca, CA		**Maine**	**$298,454**
Vallejo, CA		Lewiston, ME	
Porterville, CA		Portland, ME	
Livermore, CA		**Maryland**	**$993,652**
Colorado	**$474,260**	Aberdeen--Havre de Grace--Bel Air, MD	
Lafayette--Louisville, CO		Cumberland, MD--WV--PA	
Longmont, CO		Frederick, MD	
Boulder, CO		Hagerstown, MD--WV--PA	
Pueblo, CO		Salisbury, MD--DE	
Greeley, CO		St. Charles, MD	
Grand Junction, CO		Westminster, MD	
Florida	**$655,068**	**Massachusetts**	**$238,091**
Brooksville, FL		Leominster--Fitchburg, MA	
Fort Walton Beach, FL		**Missouri**	**$217,151**
Ocala, FL		Columbia, MO	
Panama City, FL		Joplin, MO	
Vero Beach--Sebastian, FL		**Mississippi**	**$25,000**
Georgia	**$651,815**	Pascagoula, MS	
Albany, GA		**Nevada**	**$74,885**
Athens-Clarke County, GA		Carson City, NV	
Gainesville, GA		**New Hampshire**	**$506,396**
Hinesville, GA		Manchester, NH	
Macon, GA		Dover--Rochester, NH--ME	
Rome, GA		Portsmouth, NH--ME	
Idaho	**$426,837**	Nashua, NH--MA	
Coeur d'Alene, ID		**New Mexico**	**$54,418**
Idaho Falls, ID		Farmington, NM	
Lewiston, ID--WA		**North Carolina**	**$886,211**
Nampa, ID		Concord, NC	
Pocatello, ID		Gastonia, NC	

TABLE 2 - SECTION 5307 FUEL AS CAPITAL MAINTENANCE PROVISION
STATEWIDE CAPS FOR SMALL URBANIZED AREAS (UNDER 200,000 IN POPULATION)

State / Small Urbanized Area	Program Cap	State / Small Urbanized Area	Program Cap
North Carolina, continued		**Tennessee, continued**	
Goldsboro, NC		Jackson, TN	
Greenville, NC		Johnson City, TN	
Hickory, NC		TN:Kingsport, TN--VA	
Jacksonville, NC		Morristown, TN	
Wilmington, NC		Murfreesboro, TN	
Ohio	**$765,902**	**Texas**	**$1,430,003**
Huntington, WV--KY--OH		Abilene, TX	
Lima, OH		Amarillo, TX	
Lorain--Elyria, OH		Brownsville, TX	
Mansfield, OH		College Station--Bryan, TX	
Middletown, OH		Galveston, TX	
Newark, OH		Harlingen, TX	
Sandusky, OH		Lake Jackson--Angleton, TX	
Springfield, OH		McKinney, TX	
Weirton, WV--Steubenville, OH--PA		Texas City, TX	
South Carolina	**$559,980**	Tyler, TX	
Anderson, SC		**Virginia**	**$192,505**
Spartanburg, SC		Blacksburg, VA	
Florence, SC		Bristol, TN--Bristol, VA	
Mauldin--Simpsonville, SC		Fredericksburg, VA	
Rock Hill, SC		Harrisonburg, VA	
Sumter, SC		Lynchburg, VA	
South Dakota	**$191,662**	Roanoke, VA	
Sioux Falls, SD		Winchester, VA	
Tennessee	**$226,670**	**West Virginia**	**$32,594**
Bristol, TN--Bristol, VA		Weirton, WV--Steubenville, OH--PA	
Clarksville, TN--KY			
Cleveland, TN			
		Total - Small Urbanized Areas	**$5,466,345**

BILLING CODE C

[FR Doc. 2012–8853 Filed 4–11–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Fiscal Service

Proposed Collection of Information: "Notice of Reclamation Electronic Funds Transfer, Federal Recurring Payments; and "Request for Debit, Electronic Funds Transfer, Federal Recurring Payments"

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Financial Management Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection. By this notice, the Financial Management Service solicits comments concerning forms FMS–I33, "Notice of Reclamation. Electronic Funds Transfer, Federal Recurring Payment" and FMS–135, "Request for Debit. Electronic Funds Transfer, Federal Recurring Payments."

DATES: Written comments should be received on or before June 11, 2012.

ADDRESSES: Direct all written comments to Financial Management Service, 3700 East West Highway, Records and Information Management Branch, Room 135, Hyattsville, Maryland 20782.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Kwema Ledbetter, Director, Project Management Division, Project Management Division, Room 611B, 3700 East West Highway, Hyattsville, MD 20782, (202) 874–3974.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A)), the Financial Management Service solicits comments on the collection of information described below:

Title: "Notice of Reclamation, Electronic Funds Transfer, Federal Recurring Payments"; and "Request for Debit, Electronic Funds Transfer, Federal Recurring Payments".

OMB Number: 1510–0043.

Form Number: FMS 133, FMS 135.

Abstract: Program agencies authorize Treasury to recover payments that have been issued after the death of the beneficiary. FMS Form 133 is used by Treasury to notify financial organizations (FO) of the FO's accountability concerning the funds. When an FO does not respond to the FMS 133, Treasury then prepares FMS 135 and sends it to the Federal Reserve Bank (FRB) to request that the FRB debit the FO's account.

Current Actions: Extension of currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 223,128.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 44,625.

Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: April 4, 2012.

Sheryl R. Morrow,

Assistant Commissioner, Payment Management.

[FR Doc. 2012–8588 Filed 4–11–12; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Proposed Collection of Information: Trace Request for Electronic Funds Transfer (EFT) Payment; and Trace Request Direct Deposit

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Financial Management Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection. By this notice, the Financial Management Service solicits comments concerning forms FMS–150.1 ''Trace Request for Electronic Funds Transfer Payment'' and FMS–150.2 ''Trace Request Direct Deposit.''

DATES: Written comments should be received on or before June 11, 2012.

ADDRESSES: Direct all written comments to Financial Management Service, 3700 East West Highway, Records and Information Management Branch, Room 135, Hyattsville, Maryland 20782.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Kwema Ledbetter, Director, Project Management Division, Project Management Division, Room 611B, 3700 East West Highway, Hyattsville, MD 20782, (202) 874–3974.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A)), the Financial Management Service solicits comments on the collection of information described below:

Title: Trace Request for EFT Payment; and Trace Request Direct Deposit.

OMB Number: 1510–0045.

Form Number: FMS 150.1, FMS 150.2.

Abstract: These forms are used to notify the financial organization that a customer (beneficiary) has claimed non-receipt of credit for a payment. The forms are designed to help the financial organization locate any problems and to keep the customer (beneficiary) informed of any action taken.

Current Actions: Extension of currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 59,714.

Estimated Time per Respondent: 8 minutes.

Estimated Total Annual Burden Hours: 7,961.

Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: April 4, 2012.

Sheryl R. Morrow,

Assistant Commissioner, Payment Management.

[FR Doc. 2012–8592 Filed 4–11–12; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of Inflation Adjustment Factor, Nonconventional Source Fuel Credit, and Reference Price for Calendar Year 2011

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the inflation adjustment factor, nonconventional source fuel credit, and reference price for calendar year 2011 as required by section 45K of the Internal Revenue Code (26 U.S.C. section 45K). The inflation adjustment factor is used to determine the credit allowable under section 45K for coke or coke gas (other than from petroleum based products) for calendar year 2011.

DATES: The 2011 inflation adjustment factor and nonconventional source fuel credit apply to coke or coke gas (other than from petroleum based products) sold during calendar year 2011.

Inflation Adjustment Factor: The inflation adjustment factor for coke or coke gas for calendar year 2011 is 1.1712.

Credit: The nonconventional source fuel credit for coke or coke gas for calendar year 2011 is $3.51 per barrel-of-oil equivalent of qualified fuels.

Reference Price: The reference price for calendar year 2011 is $95.73. The phase-out of the credit does not apply to coke or coke gas.

FOR FURTHER INFORMATION CONTACT:

For questions about how the inflation adjustment factor is calculated—

Ahmad Qadri, RAS:R:FDA, Internal Revenue Service, 77 K Street NE., Washington, DC 20002, Telephone Number (202) 874–5225 (not a toll-free number).

For all other questions about the credit or the reference price—

Jennifer Bernardini, CC:PSI:6, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, Telephone Number (202) 622–3110 (not a toll-free number).

Dated: April 6, 2012.

Curt G. Wilson,

Associate Chief Counsel, Passthroughs and Special Industries.

[FR Doc. 2012–8754 Filed 4–11–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0165]

Proposed Information Collection (Financial Status Report) Activity: Comment Request

AGENCY: Office of Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of Management (OM), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine a claimant's financial status.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 11, 2012.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Dawn M. Eggers, VA Debt Management Center, Bishop Henry Whipple Federal Building, P.O. Box 11930, St. Paul, MN 55111–0930 or email to: *dawn.eggers@va.gov.* Please refer to ''OMB Control No. 2900–0165'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Dawn M. Eggers at (612) 713–6361 or FAX (612) 970–5687.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, OM invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of OM's functions, including whether the information will have practical utility; (2) the accuracy of OM's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Financial Status Report, VA Form 5655.

OMB Control Number: 2900–0165.

Type of Review: Extension of a currently approved collection.

Abstract: Claimants complete VA Form 5655 to report their financial status. VA uses the data collected to determine the claimant's eligibility for a waiver of collection, setup a payment plan or for the acceptance of a compromise offer on their VA benefit debt.

Affected Public: Individuals or households.

Estimated Annual Burden: 57,155 hours.

Estimated Average Burden per Respondent: 1 hour.

Frequency of Response: On occasion.

Estimated Number of Respondents: 57,155.

Dated: April 9, 2012.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2012–8800 Filed 4–11–12; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–New (Post-9/11 GI Bill Longitudinal Study Survey)]

Proposed Information Collection (Post-9/11 GI Bill Education Longitudinal Study Survey) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine the long-term outcomes of Veterans participating in VBA's Post-9/11GI Bill program.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 11, 2012.

ADDRESSES: Submit written comments on the collection of information through the Federal Docket Management System (FDMS) at *www.Regulations.gov;* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–New (Post-9/11 GI Bill Longitudinal Study Survey)'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Post-9/11 GI Bill Longitudinal Study Survey.

OMB Control Number: 2900–New (Post-9/11 GI Bill Longitudinal Study Survey).

Type of Review: New data collection.

Abstract: VBA will collect survey data on individuals who began participating in the Post-9/11—GI Bill Chapter 33 program during fiscal years 2010, 2012, and 2014. VBA will collect and analyze the survey data to determine the long-term positive outcomes of individuals participating in VBA's Chapter 33 program. The purpose of this study is to assess the effectiveness of the Chapter 33 program, so that the VA can find ways to improve the program and increase the educational support the agency provides to Veterans and their eligible dependents.

Affected Public: Individuals and Households.

Estimated Annual Burden: 2,333 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 7,000.

Dated: April 9, 2012.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2012–8801 Filed 4–11–12; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0128]

Proposed Information Collection (Notice of Lapse—Government Life Insurance); Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to this notice. This notice solicits comments on information needed to determine claimants' eligibility to reinstate lapsed Government Life Insurance policy.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 11, 2012.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov;* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email *nancy.kessinger@va.gov.* Please refer to "OMB Control No. 2900–0128 in any correspondence. During the comment period, comments may be viewed online through FDMS at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or Fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles

a. Notice of Lapse—Government Life Insurance, VA Form 29–389.

b. Application for Reinstatement, VA Form 29–389–1.

OMB Control Number: 2900–0128.

Type of Review: Extension of a currently approved collection.

Abstract: VA Forms 29–389 and 29–389–1 are used to inform claimants that their government life insurance has lapsed or will lapse due to non payment of premiums. The claimant must complete the application to reinstate the insurance and to elect to pay the past due premiums. VA uses the data collected to determine the claimant's eligibility for reinstatement of such insurance.

Affected Public: Individuals or Households.

Estimated Annual Burden

a. VA Form 29–389—3,399 hours.

b. VA Form 29–389–1—1,060 hours.

Estimated Average Burden Per Respondent

a. VA Form 29–389—12 minutes.

b. VA Form 29–389–1—10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents

a. VA Form 29–389—16,993.

b. VA Form 29–389–1—6,359.

Dated: April 9, 2012.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2012–8802 Filed 4–11–12; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 77 Thursday,

No. 71 April 12, 2012

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422 and 423

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4157–FC]

RIN 0938–AQ86

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement new statutory requirements; strengthen beneficiary protections; exclude plan participants that perform poorly; improve program efficiencies; and clarify program requirements. It also responds to public comments regarding the long-term care facility conditions of participation pertaining to pharmacy services.

DATES: *Effective dates:* These regulations are effective on June 1, 2012 unless otherwise specified in section I.B. of this final rule with comment period (see Table 1). Amendments to the definitions of ‘‘other health or prescription drug coverage’’ at § 423.2305 and ‘‘supplemental benefits’’ at § 423.100 are effective January 1, 2013.

Comment date: We will only consider public comments on the issues specified in section II.B.5 of this final rule with comment period, Independence of LTC Consultant Pharmacists, if we receive them at one of the addresses specified in the **ADDRESSES** section of this final rule with comment period, on June 11, 2012.

Applicability dates: In section I.B. of the preamble of this final rule with comment period, we provide a table (Table 1) which lists revisions that have an applicability date other than the effective date of this final rule with comment period.

ADDRESSES: In commenting, please refer to file code CMS–4157–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ‘‘Submit a comment’’ instructions.

2. *By regular mail.* You may mail written comments to the following address *Only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4157–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4157–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments *only* to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC— Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD— Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Christian Bauer, (410) 786–6043, and Kathryn Jansak, (410) 786–9364, General information.

Christopher McClintick, (410) 786–4682, Part C issues.

Deborah Larwood, (410) 786–9500, Part D issues.

Kristy Nishimoto, (206) 615–2367, Part C and D enrollment and appeals issues.

Deondra Moseley, (410) 786–4577, Part C payment issues.

Ilina Chaudhuri, (410) 786–8628, Part D payment issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Table of Contents

Acronyms

AO Accrediting Organization
ADS Automatic Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
ANOC Annual Notice of Change
AOR Appointment of Representative
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLA Biologics License Application
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
CCS Certified Coding Specialist
CDC Centers for Disease Control
CHIP Children's Health Insurance Programs
CMR Comprehensive Medication Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DEA Drug Enforcement Administration
DIR Direct and Indirect Remuneration
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
D–SNPs Dual Eligible SNPs
DOL U.S. Department of Labor
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DUM Drug Utilization Management
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration
FEHBP Federal Employees Health Benefits Plan
FFS Fee-for-Service
FIDE Fully-Integrated Dual Eligible
FIDE SNPs Fully-Integrated Dual Eligible Special Needs Plans
FMV Fair Market Value
FY Fiscal year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
ID Identification
IPPS [Acute Care Hospital] Inpatient Prospective Payment System
IRE Independent Review Entity
IVC Initial Validation Contractor
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage-Prescription Drug Plan
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MOC Medicare Options Compare
MOOP Maximum Out-of-Pocket
MPDPF Medicare Prescription Drug Plan Finder
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MS–DRG Medicare Severity Diagnosis Related Group

MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDA New Drug Application
NDC National Drug Code
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-Coverage
NPI National Provider Identifier
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
Part C—Medicare Advantage
Part D—Medicare Prescription Drug Benefit Program
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POA Present on Admission (Indicator)
POS Point-of-Sale
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RHIA Registered Health Information Administrator
RHIT Registered Health Information Technician
RPPO Regional Preferred Provider Organization
SEP Special Enrollment Periods
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
TPA Third Party Administrator
TrOOP True Out-of-Pocket
U&C Usual and Customary
UPIN Uniform Provider Identification Number
USP U.S. Pharmacopoeia

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

a. Need for Regulatory Action

We are publishing this final rule with comment period for the Medicare Advantage (Part C) and prescription drug (Part D) programs to make changes as required by statute, including the Affordable Care Act, as well as improve the program through modifications that reflect experience we have obtained in administering the Part C and Part D programs and/or address requests for clarification received from stakeholders such as health plans and Part D sponsors. The five different sections of the preamble cover the specific means by which we believe the final rule will: (1) Implement statutory provisions; (2) strengthen beneficiary protections; (3) exclude plan participants that perform poorly; (4) improve program efficiencies; and (5) clarify program requirements.

b. Legal Authority

Our authority for this final regulation stems from the Social Security Act (the Act). As is discussed in more detail in section I.C. of this final rule with comment period, the Balanced Budget Act of 1997 (BBA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created, respectively, the Medicare Advantage (MA) program (Part C) and the Medicare Prescription Drug Benefit Program (Part D). Congress continues to amend the Act and change both Parts C and D, and this final regulation includes modifications required by, for instance, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and the Affordable Care Act.

2. Summary of the Major Provisions

a. Coverage Gap Discount Program (§ 423.100, § 423.505(b), § 423.1002, and Subpart W (§ 423.2300 Through 423.2410))

The Affordable Care Act made several amendments to Part D of Title XVIII of the Act, including adding sections 1860D–43 and 1860D–14A of the Act, and amending section 1860D–2(b) of the Act. Beginning on January 1, 2011, these amendments started phasing out the Part D coverage gap, or ''donut hole'' for Medicare beneficiaries who do not already receive low-income subsidies from CMS by establishing the Medicare Coverage Gap Discount Program (Discount Program). We implemented the Discount Program through program instructions due to the January 1, 2011 implementation deadline. Although not required, we are codifying most of the existing Discount Program requirements (that is, those that we have previously implemented through the relevant Agreements and guidance) through full notice and comment rulemaking to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

b. Pharmacy Benefit Manager's Transparency Requirements (§ 423.501 and § 423.514)

Section 1150A of the Act, as amended by section 6005 of the Affordable Care Act, requires Part D sponsors and entities that provide pharmacy benefits management services to report various data elements. The statute further specifies that this information is confidential and generally shall not be disclosed by the government or by a plan receiving the information, with certain exceptions that allow the government to disclose the information in a non-identifiable form. There are penalties for those that fail to meet the requirements of this provision. We are codifying the reporting requirements, confidentiality protections, and penalty provision in this final rule with comment period.

c. Who May File Part D Appeals With the Independent Review Entity (§ 423.600 and § 423.602)

This change to our regulations allows prescribers to request a reconsideration on an enrollee's behalf without obtaining an appointed representative form. We believe this change will make the Part D appeals process more accessible to beneficiaries. The legal authority for this policy is section 1860D–4(g) of the Act.

d. Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§§ 422.510, 423.505, and 423.509)

Each year, we issue performance quality ratings, using a 5-star system where 5 stars indicates the highest quality, of Part C and D plan sponsors. The plan ratings are based on a series of measures that correspond to operational requirements of the Part C and D programs. We have established that 3 stars reflects an average level of performance and is the lowest acceptable rating for plan sponsors. Sponsors that fail for three consecutive years to achieve at least a 3-star rating have demonstrated that they have substantially failed to meet the requirements of the Part C and D programs and failed to take timely and effective corrective action. Therefore, we are adopting the authority to terminate the contracts of Part C and D sponsors that fail to achieve at least a 3-star plan rating for 3 consecutive years. The data used to calculate the plan ratings is plan performance data that serves as evidence that the sponsor has reached the substantial failure standard that CMS must use, pursuant to section 1857(c)(2) of the Act, to make a contract termination decision.

e. New Benefit Flexibility for Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

This provision specifies that, subject to CMS approval, and as specified annually by CMS, certain dual eligible SNPs (D–SNPs) that meet integration and performance standards may offer additional supplemental benefits beyond those CMS currently allows other MA plans to offer, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population. Such benefits may include nonskilled nursing services, personal care services, and other long-term care services and supports designed to keep dual eligible beneficiaries out of institutions. We would require D–SNPs that offer these additional supplemental benefits to do so at no additional cost to the beneficiary. We believe that providing certain D–SNPs that meet integration and performance standards the flexibility to offer additional supplemental benefits could better integrate care for the dual eligible population, help prevent health status decline, and reduce the quantity and cost of future health care needs.

f. Clarifying Coverage of Durable Medical Equipment (§§ 422.100 and 422.111)

This provision permits a Medicare Advantage plan to limit durable medical equipment (DME) to specific ''preferred'' brands and manufacturers as long as the plan complies with several requirements intended to ensure that the enrollee continues to have access to all categories of DME specified in the Social Security Act. Beneficiary protections include access to all preferred brands, a transition period permitting enrollees to retain DME when changing plans, exceptions to plan limitations based on medical necessity, the ability to appeal a plan's denial of DME based on brand/manufacturer, and plan disclosure of DME limitations to enrollees.

g. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program (§§ 423.104 and 423.153)

The daily cost-sharing rate requirement provides a financial incentive to Medicare Part D beneficiaries to ask their prescribers whether less than a month's supply of a drug would be appropriate because, if so, the Part D sponsor will apply lower, pro-rated cost sharing when the prescription is dispensed, which also reduces costs and waste. Sponsors will not be required to provide daily cost-sharing rates upon request until January 1, 2014.

h. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

Part D sponsors must include an active and valid prescriber National Provider Identifier (NPI) on prescription drug event records (PDEs) that they submit to CMS, which will assist the Federal government in fighting possible fraudulent activity in the Part D program, because prescribers will be consistently and uniformly identified. This policy will not interfere with beneficiary access to needed medications because Part D sponsors must validate the NPI at point of sale, and if this is not possible, permit the prescription to be dispensed and obtain the valid NPI afterwards.

3. Summary of Costs and Benefits

Preamble section	Provision description	Total 6 year costs	Total 6 year benefits
II.A.1	Coverage Gap Discount Program (§§ 423.100, 423.505(b), 423.1002, and Subpart W (§§ 423.2300–423.2410)).	$1.3 billion: Cost to Federal government $76 M: Cost to Part D sponsors. $29.8 billion: Cost to manufacturers.	$29.7 billion in manufacturer discounts for Part D enrollees. Provides additional health benefits through increased adherence to medication regimens; and allows beneficiaries to reach the catastrophic coverage phase more quickly.
II.A.3	Pharmacy Benefit Manager's Transparency Requirements (§§ 423.501 and 423.514).	N/A (Nearly all data elements are already collected for other purposes).	Promotes PBM transparency to Part D sponsors and Medicare.
II.B.4	Who May File Part D Appeals with the Independent Review Entity (§ 423.600).	$5.84 million: Cost to Federal government. $450,000: Cost to Part D sponsors.	Improves beneficiary access to the Part D appeals process.
II.C.2	Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§§ 422.510, 423.505, and 423.509).	N/A	*For beneficiaries:* Provides assurance that they are making a plan election from among only those sponsors that demonstrate a commitment to providing high quality service. *For CMS:* Emphasizes further CMS' commitment to driving improvement in the health care and prescription drug benefit markets.
II.D.2	New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D-SNPs) (§ 422.102).	$0.36 million to MA organizations	For beneficiaries: The flexibility for certain D–SNPs to offer additional supplemental benefits is in keeping with our objective of keeping Medicare-Medicaid (''dual eligible'') beneficiaries who are at risk of institutionalization in the community. For CMS: $135.1 million in savings that accrue to the Federal Medicaid program and the Medicare program. For States: $2.62 million in savings to the State Medicaid program.

Preamble section	Provision description	Total 6 year costs	Total 6 year benefits
II.D.4	Clarifying Coverage of Durable Medical Equipment (§§ 422.100 and 422.111).	N/A	N/A.
II.D.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program (§§ 423.100, 423.104 and 423.153).	$0.5 million: cost to Part D sponsors	Over $1.8 billion in estimated savings to the Part D program. Savings to beneficiaries who take advantage of option in consultation with their prescribers through lower cost-sharing for prescriptions. Reduction of medication waste.
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120).	$30.7 million: cost to Part D sponsors	Improved capability to fight fraud in the Medicare Part D program.

B. Effective and Applicability Dates

We note that these regulations will be effective 60 days after the publication of this final rule with comment period, except for two regulations whose effective dates are mandated by statute and one regulation whose effective date we are choosing to delay. Section 175(b) of MIPPA provides that barbiturates for specified health conditions and benzodiazepines be considered as Part D drugs for prescriptions dispensed on or after January 1, 2013. Similarly, section 10328 of the Affordable Care Act requires that, for plan years beginning on or after 2 years after the date of its enactment, Part D sponsors offer to targeted beneficiaries annual comprehensive medication reviews (CMRs). The Affordable Care Act was enacted on March 23, 2010; accordingly, the revision regarding CMRs in LTC settings will become effective January 1, 2013. Additionally, we have delayed the effective date of the change to the policy on who may file Part D appeals with the Independent Review Entity to clarify that physicians and other prescribers may not request reconsiderations on behalf of beneficiaries until the beginning of the 2013 plan year (unless they are the beneficiary's authorized representative).

Unless specified in this final rule with comment period, the effective date and the applicability date are the same. There are some instances in which they may vary. For instance, because the health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, some provisions will not be applicable prior to contract year January 1, 2013. In Table 1 we provide a list of revisions whose applicable dates vary from the effective date of 60 days after publication of this final rule with comment period.

TABLE 2—FINALIZED REVISIONS WITH EFFECTIVE AND/OR APPLICABLE DATES OTHER THAN 60 DAYS AFTER PUBLICATION

Preamble section	Section title	Effective date applicability date
II.A.1	Coverage Gap Discount Program	The definition of "other health or prescription drug coverage" under § 423.2305 and change to the existing definition of "supplemental benefits" under § 423.100 are: effective 60 days after date of publication applicable 01/01/13 **Note:** All remaining regulations related to the Coverage Gap Discount Program remain: Effective 60 days after date of publication applicable 60 days after date of publication
II.A.2	Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs.	effective 01/01/13 applicable 01/01/13
II.B.1	Good Cause and Reinstatement into a Cost Plan	effective 60 days after date of publication applicable 01/01/13
II.B.2	Requiring MA plans to disclose Member ID cards	effective 60 days after date of publication applicable 01/01/13
II.B.4	Clarifying Who May File Part D Appeals with the Independent Review Entity.	effective and applicable 01/01/13
II.C.1	CMS Termination of Health Care Prepayment Plans	effective 60 days after date of publication applicable 01/01/13
II.D.1	Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal.	effective 60 days after date of publication applicable 01/01/13
II.D.2	Flexibilities for Certain Fully-Integrated Dual Eligible Special Needs Plans.	effective 60 days after date of publication applicable 01/01/13
II.D.4	Clarifying Coverage of Durable Medical Equipment	effective 60 days after date of publication applicable 01/01/13
II.D.5	Broker and Agent Requirements	effective 60 days after date of publication applicable 01/01/13
II.E.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program.	effective 60 days after date of publication applicable 01/01/14
II.E.2	Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans.	effective 60 days after date of publication applicable 01/01/13

TABLE 2—FINALIZED REVISIONS WITH EFFECTIVE AND/OR APPLICABLE DATES OTHER THAN 60 DAYS AFTER PUBLICATION—Continued

Preamble section	Section title	Effective date applicability date
II.E.3	Clarification of, and Extension of Regional Preferred Provider Organization Plan Single Deductible Requirements to, Local Preferred Provider Plans.	effective 60 days after date of publication applicable 01/01/13
II.E.4	Technical Change to Private Fee-For-Service Plan Explanation of Benefits Requirements.	effective 60 days after date of publication applicable sometime after 2013 application cycle (when EOB model for all MA plans are finalized)
II.E.5	Application Requirements for Special Needs Plans	effective 60 days after date of publication applicable 01/01/13
II.E.6	Timeline for Resubmitting Previously Denied MA Applications	effective 60 days after date of publication applicable 01/01/13
II.E.7	Clarification of Contract Requirements for First Tier and Downstream Entities.	effective 60 days after date of publication applicable 01/01/13
II.E.9	Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings.	effective 01/01/13 applicable 01/01/13
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers.	effective 60 days after date of publication applicable 01/01/13

C. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Act) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 1860D–42 of the Act) entitled the Medicare Prescription Drug Benefit Program, and made significant changes to the existing Part C program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the January 28, 2005 **Federal Register** (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, in September 2008 and January 2009, we issued Part C and D regulations (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881). In April 2010, we issued Part C and D regulations (75 FR 19678) which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented changes to the Part C and Part D programs made by then-recent legislative changes.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152) are collectively referred to as the Affordable Care Act. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on provisions enacted in the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

In the October 11, 2011 **Federal Register** (76 FR 63018), we published a proposed rule with proposed revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D). The goals of this proposed rule were to: Implement provisions from the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA); strengthen beneficiary protections; exclude plan participants that perform poorly; improve program efficiencies; and clarify program requirements for contract year 2013. The proposed rule also included consideration of changes to the long term care facility (LTC) conditions of participation relating to pharmacy services.

II. Provisions of the Proposed Rule and Analysis and Response to Public Comments

We received approximately 516 items of timely correspondence containing comments on the proposed rule published in the October 11, 2011 **Federal Register** (76 FR 63018). Commenters included health and drug plan organizations, insurance industry trade groups, provider associations, pharmacists (including consultant pharmacists) and pharmacy associations, representatives of hospital and long term care institutions, pharmacy benefit managers, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, private citizens, ombudsmen, and others.

In this final rule with comment period, we address all comments and concerns regarding the policies included in the proposed rule. We also reference, in the comment and response sections of this final rule with comment period, some comments that were outside the scope of the revisions we proposed in October 2011. We present a summary of public comments, as well as our responses to them in the applicable subject-matter sections of this final rule with comment period.

In the sections that follow, we discuss finalized revisions to the regulations in 42 CFR parts 417, 422, and 423 which govern the MA and prescription drug benefit programs. We also considered—but for the present decided against—making changes to the regulations setting forth the Medicare conditions of participation for long-term care facilities, which are currently codified at 42 CFR part 483. The preamble for the final rule will follow the structure of the October 2011 proposed rule and cover issues by topic area. Accordingly, our proposals address the following five specific goals:

- Implementing provisions of MIPPA and the Affordable Care Act.
- Strengthening beneficiary protections.
- Excluding poor performers.
- Improving program efficiencies.
- Clarifying program requirements.

Several of the proposed revisions and clarifications affect both the MA and prescription drug programs, while a few affect cost contracts under section 1876 of the Act. Within each of the five major sections of the preamble to this final rule with comment period, we discuss provisions in order of appearance in the associated regulations; a chart at the beginning of each of the five sections provides subsection numbers and titles and the associated regulatory citations. Although we are not finalizing all the revisions proposed, discussion (including comments and responses) of non-finalized proposals will still appear in the same order as was the case in the October 2011 proposed rule.

A. Implementing Statutory Provisions

We are finalizing all three provisions in this section, two of which implement sections of the Affordable Care Act and one which implements a MIPPA mandate. In this final rule with comment period, we consolidate and codify previous guidance regarding the Coverage Gap Discount Program mandated by the Affordable Care Act. We believe this consolidation will provide stakeholders a central, clear source of direction. We are also finalizing regulations under a MIPPA provision which will provide treatment for beneficiaries who require benzodiazepines and, as specified, barbiturates. Lastly, we are finalizing regulations implementing section 6005 of the Affordable Care Act, which contains several reporting requirements for Part D sponsors and entities that provide pharmacy benefits management services to Part D sponsors. The changes based on provisions in the Affordable Care Act and MIPPA are detailed in Table 2.

TABLE 2—PROVISIONS TO IMPLEMENT STATUTORY PROVISIONS

Preamble section	Provision	Part 423	
		Subpart	Section(s)
II.A.1	Coverage Gap Discount Program	Subpart C Subpart K Subpart T Subpart T Subpart W (new)	423.100 423.505 423.1000 423.1002 423.2300–423.2345
II.A.2	Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	Subpart C	423.100
II.A.3	Pharmacy Benefit Manager's Transparency Requirements	Subpart K	423.501 423.514

1. Coverage Gap Discount Program (§§ 423.100, 423.505(b), 423.1000, 423.1002, and 423.2300 Through 423.2345 (Subpart W))

Section 3301 of the Affordable Care Act made several amendments to Part D of Title XVIII of the Act, including adding sections 1860D–43 and 1860D–14A of the Act, and amending section 1860D–2(b) of the Act. Beginning on January 1, 2011, these amendments started phasing out the Part D coverage gap, or ''donut hole'' for Medicare beneficiaries who do not already receive low-income subsidies from CMS by establishing the Medicare Coverage Gap Discount Program (Discount Program) and gradually increasing coverage in the coverage gap for both generic drugs (beginning in 2011) and brand name drugs and biological products (beginning in 2013). By 2020, beneficiary cost-sharing for applicable beneficiaries for all covered brand-name and generic drugs and biological products after the deductible will equal 25 percent until they reach catastrophic coverage.

The Discount Program makes manufacturer discounts available at the point-of-sale to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. In general, the discount on each applicable drug is 50 percent of an amount equal to the negotiated price of the drug (less any dispensing fee). In general, manufacturers must agree to provide these discounts by signing an agreement with CMS in order for their applicable drugs to continue to be covered under Medicare Part D. We note that we have authority under section 1860D–43(c) of the Act to make an exception that allows coverage without an agreement, but based on the current level of participation by manufacturers and the breadth of applicable drugs covered by Discount Program Agreements, we do not anticipate needing to exercise such authority.

While manufacturer discounts under the Discount Program must be made available at point-of-sale, the Affordable Care Act does not specify how this should be done. At the same time, it prohibits us from receiving or distributing any funds of the manufacturer under the program. In order to provide point-of-sale discounts, we determined that an entity must have the information necessary to determine at that point in time that the drug is discountable, the beneficiary is eligible for the discount, the claim is wholly or partly in the coverage gap, and the amount of the discount, taking into consideration negotiated plan prices and that plan supplemental benefits must pay before the discount amount can be determined. We determined that the only entities that have the information necessary to provide point-of-sale discounts under the Discount Program are Part D sponsors. Only the Part D sponsor knows which Part D drugs are on its formulary and which enrollees have obtained an exception to receive a non-formulary Part D drug. The Part D sponsor has the low-income subsidy (LIS) information for beneficiaries that is necessary to exclude such claims from the Discount Program. The Part D sponsor tracks gross drug spend and TrOOP costs, which are necessary for determining when the beneficiary enters and exits the coverage gap. In addition, only the Part D sponsor knows which portion of the claim is in the coverage gap. For these reasons, we have determined that the Part D sponsor can accurately provide the discount at point-of-sale.

Section 1860D–14A(d)(5) of the Act authorizes us to implement the Discount Program through program instruction. We used this authority to issue program guidance to Part D sponsors on May 21, 2010, with an abbreviated notice and comment period, instructing them to provide applicable discounts on applicable drugs to applicable beneficiaries at point-of-sale beginning on January 1, 2011. The guidance also specified that Part D sponsors would report discount amounts to us, that we would invoice manufacturers on a quarterly basis for these discounts, and that the manufacturers would repay each Part D sponsor directly for the invoiced discount provided on the manufacturers' behalf. We determined that this model was necessary because Part D sponsors needed to provide the discounts at point-of-sale (as explained previously) and we needed to coordinate the discount payments between manufacturers and Part D sponsors to ensure discounts were appropriately provided by the Part D sponsors and reimbursed by the manufacturers without directly receiving or distributing manufacturer funds (which we are prohibited from doing by section 1860D–14A(d)(2)(A) of the Act).

We implemented the Discount Program through program instruction due to the January 1, 2011 implementation deadline. Although not required, we are codifying most of existing Discount Program requirements (that is, those that we have previously implemented through the relevant Agreements and guidance) through full notice and comment rulemaking to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

a. Scope (§ 423.2300)

Subpart W of part 423 implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements as follows:

- Condition of coverage of drugs under Part D.
- The Medicare Coverage Gap Discount Program Agreement.
- Coverage gap discount payment processes for Part D sponsors.
- Provision of applicable discounts on applicable drugs for applicable beneficiaries.
- Manufacturer audit and dispute resolution processes.
- Resolution of beneficiary disputes involving coverage gap discounts.
- Compliance monitoring and civil money penalties.
- The termination of the Discount Program Agreement.

In this section, we summarize the provisions of subpart W and respond to public comments.

b. Definitions (§ 423.2305)

Proposed § 423.2305 included definitions for terms that are frequently used in this subpart. Those terms we believe need additional clarification are described separately in this section of the final rule with comment period.

(1) Applicable Beneficiary

Applicable beneficiary is defined in § 423.100. We clarify that enrollees in employer-sponsored group prescription drug plans (as defined in § 423.454) may qualify as applicable beneficiaries.

(2) Applicable Drug

Applicable drug is defined in § 423.100. We clarify that applicable drugs include all covered Part D drugs marketed under a new drug application (NDA) or biologics license application (BLA) (other than a product licensed under section 351(k) of the Public Health Service Act). This means that such drugs and biological products would be subject to an applicable discount in the coverage gap even if a Part D sponsor otherwise treats the product as a generic under its benefit. Conversely, covered Part D drugs that are marketed under trade names and generally thought of as brand-name drugs or biological products, but are not approved under an NDA or licensed under a BLA (other than a product licensed under section 351(k) of the Public Health Service Act), are not applicable drugs that would be subject to an applicable discount in the coverage gap. Finally, drugs excluded from Part D under section 1860D–2(e)(2)(A) of the Act are not covered Part D drugs and therefore, such drugs would not be applicable drugs subject to an applicable discount even if covered by the Part D sponsor under an enhanced benefit. Part D sponsors would need to make these determinations on a National Drug Code (NDC) by NDC basis.

The second part of the definition provides that an applicable drug is either available on-formulary if a Part D sponsor uses a formulary, or available under the benefits provided by a Part D sponsor that does not use a formulary, or available to a particular beneficiary through an exception or appeal for that particular beneficiary. Applicable drugs covered under transition requirements and emergency fill policies are considered covered through an exception and, therefore, would be subject to applicable discounts.

In addition, we interpret the definition of an applicable drug for purposes of the Discount Program to exclude Part D compounds. While Part D sponsors may cover compounds with at least one Part D drug ingredient, and that ingredient would be an applicable drug if dispensed on its own, in light of the operational difficulty in accurately determining which portion(s) of a Part D compound represents the Part D drug, we believe that the applicable drug determination must be made with respect to the compound as a whole. Given that a compound as a whole is not approved under an NDA or BLA, a compound does not meet the definition of an applicable drug.

(3) Incurred Costs

Section 3301 of the Affordable Care Act amends section 1860D–2(b)(4) of the Act by adding subparagraph (E) when applying subparagraph (A) to include the negotiated price (as defined in paragraph (6) of section 1860D–14A(g) of the Act) of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under Medicare Coverage Gap Discount Program regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D) (that is, gap coverage). Therefore, we proposed to revise the definition of incurred costs in § 423.100 by adding the following language to paragraph (2)(ii) of such definition—''or by a manufacturer as payment for an applicable discount (as defined § 423.2305) under the Medicare Coverage Gap Discount Program (as defined in § 423.2305)''. This would mean that all applicable discounts paid by manufacturers would be treated as incurred costs for purposes of calculating the beneficiary's TrOOP.

(4) Manufacturer

Section 1860D–14A(g)(5) of the Act defines manufacturer under the Discount Program as any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. We proposed to adopt this statutory language in § 423.2305 and also add the following clarifying language ''but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer for use.'' We proposed adding this language to the definition to track the defined term in the Discount Program Agreement, and because we believe this is the only practical way to define manufacturer under the Discount Program so that we can accurately assign responsibility for the discounts. While applicable drugs may actually be made by a limited number of companies, many more companies commonly label, relabel or repackage drug products and market them with unique labeler codes. It would be very difficult, if not impossible, to track all labeled, relabeled or repackaged products back to the original maker of the drug if we limited the definition of manufacturer to the original maker. Therefore, for purposes of the Discount Program, we interpret the definition of ''manufacturer'' in § 423.2305 to mean any company associated with a unique labeler code included in the NDCs of the applicable drugs dispensed by pharmacies.

Applicable drugs are generally marketed with labels that include the product's NDC number. In any NDC, the labeler code segment uniquely corresponds to a single company. While the same applicable drug may be marketed by multiple companies, only one company is linked to a unique labeler code. All manufacturers of applicable drugs, meaning all companies that label applicable drugs with unique labeler codes, would be required to sign an agreement for any applicable drugs with such labeler codes to be covered under Medicare Part D as of January 1, 2011. Only one manufacturer would be identified with each labeler code and, therefore, only one manufacturer would be responsible for paying applicable discounts associated with that labeler code at any given time.

(5) Medicare Part D Discount Information

In accordance with section 1860D–14A(d)(3)(C) of the Act, we require the TPA to provide adequate and timely information to manufacturers, consistent with the Discount Program Agreement with the manufacturers, as necessary for the manufacturer to fulfill its obligations under the Discount Program. Accordingly, we require the TPA to invoice each manufacturer each quarter on behalf of Part D sponsors for the applicable discounts advanced by the Part D sponsors to applicable beneficiaries and reported to CMS on the prescription drug event (PDE) records. The TPA also provides information to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on PDE records as determined by CMS. We proposed to define this information in § 423.2305 as Medicare Part D Discount Information.

Generally, the Medicare Part D Discount Information would include certain claim-level detail derived from the PDE record. Information such as applicable drug NDC, dispensing pharmacy, quantity dispensed, date of service, days supply, prescription and fill number, and reported gap discount would be provided. We would provide this information so that a manufacturer could evaluate the accuracy of claimed discounts and resolve disputes concerning the manufacturer's payment obligations under the Discount Program.

Under the current Medicare Coverage Gap Discount Program Agreement with manufacturers, ''Medicare Part D Discount Information'' refers to the information derived from applicable data elements available on PDEs and set forth in Exhibit A of the Agreement that will be sent from the TPA to the manufacturer along with each quarterly invoice. However, we proposed to apply CMS's cell-size suppression policy to the information we would release to manufacturers when 10 or fewer beneficiaries with the same applicable drug (identified as having the same first 2 segments of NDC) have claims at the same pharmacy (''low-volume claims''). Specifically, we proposed to withhold the pharmacy identifier information for these claims as an additional safeguard for preventing manufacturers from receiving information that could potentially be used to identify beneficiaries.

(6) Negotiated Price

We proposed to define negotiated price for purposes of the Discount Program consistent with section 1860D–14A(g)(6) of the Act, which defines ''negotiated price'' in terms of its meaning in § 423.100 as of the date of enactment of the section (that is, as of March 23, 2010), except that such definition does not include dispensing fees. Part D vaccine administration fees would be excluded from the definition of negotiated price for purposes of the Discount Program because we believe that, for purposes of the Discount Program, they are analogous to dispensing fees, which are explicitly excluded from the definition of negotiated price for purposes of determining the applicable discount. Unlike sales tax, dispensing fees and vaccine administration fees pay for services apart from the applicable drug itself. This is made clear by the fact that a vaccine administration fee may be billed separately from the dispensing of the vaccine. Sales tax remains included in the definition of negotiated price under the Discount Program. Thus, we proposed to define ''negotiated price'' for purposes of the Discount Program and this subpart as: the price for a covered Part D drug that—(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and (3) excludes any dispensing fee or vaccine administration fee for the applicable drug.

Further, although the statutory definition speaks only to the negotiated price with respect to a network pharmacy, given that there is no limitation on an applicable beneficiary's entitlement to applicable discounts on applicable drugs obtained out-of-network, we do not believe Congress intended to exclude these discounts from the Discount Program. Therefore, we proposed to specify in § 423.2305 that the negotiated price also means, for purposes of out-of-network claims, the plan allowance as determined under § 423.124, less any dispensing fee and vaccine administration fee.

(7) Other Health or Prescription Drug Coverage

Section 1860D–14A(c)(1)(A)(v) of the Act requires that the applicable discount get applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. Section 423.2305 of the proposed rule would define the term ''other health or prescription drug coverage'' as any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. This would include any programs that provide coverage or financial assistance outside of Part D. Thus, the applicable discount would apply before any ''other health or prescription drug coverage'' such as state pharmaceutical assistance programs (SPAPs), Aids Drug Assistance Programs (ADAPs), Indian Health Service, or supplemental coverage required by the Commonwealth of Puerto Rico.

In addition, we proposed to include in the definition of ''other health or prescription drug coverage'' any coverage offered through employer group health or waiver plans (EGWPs) other than basic prescription drug coverage as defined in § 423.100. We also proposed to make a conforming change to the definition of supplemental benefits in § 423.100 to exclude benefits offered by EGWPs. With respect to EGWPs, this would mean that a manufacturer discount always would be applied before any additional coverage beyond Part D, whether offered by the EGWP itself or by another party. We believe a clear standard in this regard is necessary to ensure we can properly administer the Discount Program for EGWP enrollees in light of our existing policies and procedures with respect to EGWPs.

Comment: A commenter recommended that we allow the determination of ''applicable drug'' status to be based upon plan formulary categorization as ''brand name'' or ''generic'' as opposed to being based upon the FDA approved marketing category.

Response: We disagree with this commenter. Section 1860D–14A(g)(2) of the Act clearly defines an applicable drug based upon its FDA marketing category as approved under a new drug application or licensed under a biologics license application. The definition proposed in § 423.2305 is consistent with the statute, and we do not have the authority to define it differently based upon formulary categorization.

Comment: A commenter supported our exclusion of Part D compounds from the definition of an applicable drug. However, another commenter stated that our exclusion of compounds from the definition of applicable drug was inconsistent with including compounds in the definition of a Part D drug.

Response: We disagree with the commenter that stated our exclusion of compounds from the definition of ''applicable drug'' was inconsistent with including compounds in the definition of a Part D drug. Whereas Part D sponsors can accurately determine that a compound has at least one Part D ingredient and the costs associated with such ingredient(s), we believe there are additional complexities associated with trying to accurately determine and validate discounts on an ingredient-level basis that require us to consider the compound as a whole for purposes of the Discount Program. Moreover, because a compound as a whole is not approved by the FDA under a new drug application or licensed under a biologics license application, a compound does not meet the definition of an applicable drug.

Comment: A few commenters supported our proposal to withhold specific data elements from the Medicare Part D Discount Information for low-volume claims. However, several commenters opposed our proposal. These commenters emphasized that the Medicare Part D Discount Information does not include any identifying beneficiary information and that under the Discount Program Agreement, manufacturers cannot: (1) link Medicare Part D Discount Information to any other data; or (2) use Medicare Part D Discount Information for purposes unrelated to the Coverage Gap Discount Program, such as to identify beneficiaries. They believe that all of the Medicare Part D Discount information is necessary to accurately validate claims and to determine that a drug was appropriately covered under Medicare Part D as opposed to Medicare Part B.

Response: We appreciate all of the comments and have decided not to finalize the proposal to withhold additional data elements for low-volume claims. This proposal was intended to codify a prior CMS policy to withhold certain data elements on low-volume claims that has since changed and is no longer applicable.

Comment: A number of commenters requested that CMS change the definition of negotiated price under the Coverage Gap Discount Program to include dispensing and vaccine administration fees so that it is consistent with the other phases of the benefit. Further, they recommended that if the definition is not changed, we require point-of-sale notice that the dispensing fee or vaccine administration fee is not discounted and also include similar language on the explanation of benefits.

Response: Section 1860D–14A(g)(6) of the Affordable Care Act defines ''negotiated price'' for purposes of the Coverage Gap Discount Program and gap coverage in terms of its meaning in § 423.100 as of the date of enactment of the section (that is, as of March 23, 2010), except that such definition does not include dispensing fees. Since the statute clearly excludes dispensing fee from the definition, we do not have the authority to include it in the definition. As for vaccine administration fees, we continue to believe that, for purposes of the Discount Program, they are analogous to dispensing fees and, therefore, do not fall within the definition of ''negotiated price.''

We also believe it is neither necessary nor practical to require beneficiary notification on every discounted claim that the beneficiary is responsible for paying the entire dispensing fee or vaccine administration fee. Electronic pharmacy transactions processed under the Health Insurance Portability and Accountability (HIPAA) approved National Council for Prescription Drug Programs electronic standard do not provide pharmacies with sufficient information at point-of-sale to know whether the beneficiary is paying the dispensing fee on a claim. Nevertheless, we understand there is a need for more clarification with respect to beneficiary liability for dispensing and vaccine administration fees for applicable drugs in the coverage gap and thus have provided guidance in the 2013 Advance Notice clarifying how manufacturer, beneficiary, and Part D sponsor liabilities, including dispensing fee liabilities, for coverage gap claims must be determined beginning in 2013.

Comment: Several commenters supported our proposal to define all supplemental benefits offered by employer group waiver plans (EGWPs) as other health or prescription drug coverage that are not Part D benefits. However, a few commenters opposed the proposal and contend that CMS does not have the authority to adopt this proposal and that it would be imprudent to adopt the proposal even if CMS had the authority to do so. They state that CMS cannot use its waiver authority under section 1860D–22(b) of the Act because it is not a waiver of a requirement that hinders the design of, the offering of, or the enrollment in employer sponsored coverage.

Response: We disagree with the commenters who believe that we do not have the authority to exclude any coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, from the definition of Part D supplemental benefits and, therefore, treat them as other health or prescription drug coverage. Under current waivers authorized by section 1860D–22(b) of the Act, EGWP sponsors submit only one formulary and a standard-defined benefit package for review by CMS. We waived the requirement for EGWPs to submit final benefit packages and formularies because we believe upholding the requirement would hinder the design, offering, or enrollment in employer-sponsored coverage given the additional complexity and level of effort that would be required of EGWPs to submit all applicable information on all such benefit packages. Consequently, we have never reviewed any supplemental benefits offered through EGWPs as Part D benefits nor have we provided guidance that such benefits are Medicare or non-Medicare benefits. In the absence of such guidance, we are aware that some EGWPs previously may have considered these supplemental benefits to be Medicare benefits while others may have considered them to be non-Medicare benefits.

As discussed in the proposed rule, the Discount Program now makes it crucial to be able to distinguish Part D benefits (which apply before the applicable discount) from non-Medicare benefits (which apply after the applicable discount). In order to make this distinction consistently and accurately, we believe it is necessary to define all such supplemental benefits as other health or prescription drug coverage because requiring submission of benefit packages would hinder the design of, the offering of, or the enrollment in employer-sponsored coverage for the same reasons that we currently waive the requirement for EGWPs to submit final benefit packages and formularies as well as a high probability that many of these supplemental benefits are also governed by other non-Medicare rules (for example ERISA) and collective bargaining agreements that could make it difficult to comply with Part D rules. Moreover, while the submission requirement itself would be a hindrance, the effort required to restructure benefits to provide all additional gap coverage as other coverage in order to maximize discounts, which we could not prevent, would add costs and complexity to the provision of EGWP coverage and, therefore, additionally hinder the design and offering of employer sponsored coverage. Accordingly, we believe it is necessary to use the waiver authority under section 1860D–22(b) of the Act to explicitly exclude any supplemental benefits offered through EGWPs (which we do not review and have never reviewed) from Part D supplemental benefits and define them as other health or prescription drug coverage.

Comment: Several commenters requested that we clarify the effective date for defining any coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, as other health or prescription drug coverage is January 1, 2013.

Response: We clarify that, beginning on January 1, 2013, EGWP supplemental benefits over basic Part D coverage must be treated as other health or prescription drug coverage. We are designating January 1, 2013 as the applicable date of this requirement in order to avoid midyear disruptions of operations for any EGWPs that currently treat supplemental benefits as Medicare benefits and therefore, calculate the discount after applying such benefits. This will provide them time to align their systems to meet the January 1, 2013 requirements.

Comment: A commenter requested that CMS clarify that coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, will be defined as other health or prescription drug coverage only for purposes of the Coverage Gap Discount Program but not for other purposes such as appeals and grievances.

Response: Beginning January 1, 2013, any coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, will be defined as other health or prescription drug coverage and not considered Medicare benefits. This definition applies to all of Medicare Part D and is not limited to the Discount Program. While the Discount Program triggered our decision to explicitly exclude supplemental coverage offered through EGWPs from Part D supplemental benefits, we believe it is necessary to apply the exclusion more broadly for the same reasons it is necessary under the Discount Program. Specifically, because we do not receive and review these benefits we cannot appropriately oversee their provision and requiring submission of these benefits needs to be waived because we believe it would hinder the design of, offering, or enrollment in employer sponsored coverage. Therefore, other Medicare Part D requirements, such as those related to appeals and grievances, will not apply to these non-Medicare benefits.

After consideration of the public comments received, we are finalizing these definitions with one modification. We are not finalizing our proposal to withhold some of the Medicare Part D Discount Information from manufacturers on low-volume claims. All definitions will be effective and applicable 60 days after publication of the rule, except for the definition of ''other health or prescription drug coverage'' found in § 423.2305 and the conforming change to the definition of supplemental benefits in § 423.100 to exclude benefits offered by EGWPs, which definition and change to an existing definition will on January 1, 2013.

c. Condition for Coverage of Drugs Under Part D (§ 423.2310)

Section 1860D–43(a) of the Act specifies that in order for coverage under Part D to be available for the covered Part D drugs (as defined in section 1860D–2(e) of the Act)) of a manufacturer, that manufacturer must agree to participate in the Discount Program, enter into a Discount Program Agreement, and enter into an agreement with the TPA. Although the statute contemplates that all manufacturers of covered Part D drugs must sign Discount Program Agreements in order for coverage under Part D to be available for such drugs, when read in context with the other provisions governing the Discount Program, we believe the plainest reading of section 1860D–43(a) of the Act is both inappropriate and infeasible. Thus, in implementing the Discount Program last year, we specified in program guidance that the exclusion from Part D coverage applies only to the applicable drugs of a manufacturer that fails to sign the Agreement and participate in the Discount Program. We currently apply the exclusion from Part D coverage only to a manufacturer's applicable drugs. Other Part D drugs, such as generic drugs (as defined in § 423.4) of a manufacturer continue to be covered under Medicare Part D irrespective of the manufacturer's participation in the Discount Program. We proposed to codify this policy in regulations.

Section 1860D–43(c)(1) of the Act authorizes us to allow coverage for drugs that are not covered by Discount Program Agreements if we have made a determination that the availability of the drug is essential to the health of beneficiaries under this part, and we proposed to codify this requirement in § 423.2310(b) of our proposed rule. However, we believe it is highly unlikely that we will need to exercise this authority given the strong participation by manufacturers in the Discount Program since 2011 and the likely availability of therapeutic alternatives for any Part D drugs.

Comment: Many commenters supported our proposal to exclude only applicable drugs that are not covered by a signed manufacturer agreement from Medicare Part D and continue to allow coverage of other Part D drugs, such as generic drugs, irrespective of a manufacturer's participation in the Coverage Gap Discount Program. However, a commenter recommended that we delay codifying this proposal until the Discount Program is fully implemented and until evidence exists that manufacturers plan to continue participating in the Discount Program.

Response: We agree with commenters that supported our proposal and do not believe it is necessary to delay codifying it until there has been more experience with the Discount Program. We believe it is important to codify this provision now to provide certainty about our policy.

After consideration of the public comments received, we are finalizing the policies in this section without modification except for the technical correction to § 423.2315(b)(7) that clarifies manufacturers must provide timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

d. Medicare Coverage Gap Discount Program Agreement (§ 423.2315)

Section 1860D–14A of the Act requires us to enter into agreements with manufacturers that participate in the Discount Program and to establish a model agreement in accordance with terms specified under section 1860D–14A(b) of the Act that provides for the performance of duties required under section 1860D–14A(c)(1) of the Act. In consultation with manufacturers, we established the model agreement on August 1, 2010 and proposed to codify in § 423.2315 provisions that we believe must be included in the model agreement in order to meet the statutory requirements in these sections.

(1) Obligations of the Manufacturer

Section 1860D–14(A)(b)(1) of the Act specifies that the Discount Program Agreement between CMS and the manufacturers shall require manufacturers to provide applicable beneficiaries access to applicable discounts for applicable drugs of the manufacturer at the point-of-sale. In light of how the Discount Program has been structured (see the discussion in section II.A.1. of the October 11, 2011 proposed rule) (76 FR 63018) we proposed to implement this requirement as set forth in the current Discount Program Agreement. That is, we proposed in § 423.2315(b)(2) to require manufacturers to reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) that were invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors and used by the TPA to calculate the invoice.

In order for CMS and Part D sponsors to determine which applicable drugs are covered by Discount Program Agreements, the manufacturers must provide CMS in advance with the FDA-assigned labeler code(s) for all applicable drug NDCs covered by their Discount Program Agreement. Under the current Discount Program Agreement, manufacturers must provide all of their labeler codes to CMS and must promptly update CMS with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA. We included this requirement in the Discount Program Agreement because, for the reasons previously described, it is the most efficient and accurate way to track which manufacturer is responsible for paying the applicable discount for an applicable drug and to assist Part D sponsors in determining which drugs are applicable drugs. We maintain an up-to-date listing of the labeler codes covered under the Discount Program Agreements on the CMS Web site so that Part D sponsors can determine which labeler codes are covered by a Discount Program Agreement. To ensure that we have up-to-date information for this purpose, § 423.2315(b)(4) would require manufacturers to provide CMS with all labeler codes for all the manufacturer's applicable drugs and promptly update CMS with additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

To permit CMS and Part D sponsors to accurately identify applicable drugs, we proposed to codify the requirement set forth in the Discount Program Agreement that manufacturers electronically list and maintain an up-to-date electronic listing of all NDCs of the manufacturer, including the timely removal of discontinued NDCs, in the FDA NDC Directory. We believe this requirement will help ensure that all currently marketed applicable drugs are subject to the applicable discount and that only currently marketed applicable drugs are subject to the discount. Because manufacturers know the regulatory and marketing status of their products, they are in the best position to make this information available to Part D sponsors and CMS. We believe maintaining an up-to-date FDA electronic listing provides the most efficient, timely, and authoritative mechanism to accomplish this purpose while placing little additional burden on manufacturers that already must use the FDA electronic registration and listing system to comply with other FDA requirements. In this final rule with comment period, we are making a technical correction to this requirement by specifying that manufacturers provide timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution. This language replaces the requirement that manufacturers timely remove discontinued NDCs in the FDA NDC Directory because we realized that it is the FDA that makes the determination to remove NDCs based upon information provided by the manufacturer.

We also proposed to require manufacturers to maintain up-to-date NDC listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Part D sponsors and the rest of the pharmacy industry rely upon these databases for adjudication of pharmacy claims at the point-of-sale, including discounting applicable drugs, and, therefore it is imperative that the information in these databases is accurate and up-to-date. Our proposal would require manufacturers to ensure that electronic database vendors are prospectively notified of expiration dates for NDCs of products that are no longer available on the market. We believe this requirement will benefit manufacturers because it will ensure that applicable discounts cease being applied as of the last lot expiration date of an applicable drug that is no longer on the market.

In implementing the Discount Program Agreement, we required manufacturers to pay each Part D sponsor in the manner specified by us within 38 calendar days of receipt of an invoice and Medicare Part D Discount Information for the quarterly applicable discounts included on the invoice. As previously described, we implemented the Discount Program such that Part D sponsors pay applicable discounts on behalf of manufacturers in order to comply with the statutory mandate that discounts be provided at the point-of-sale, and therefore we require manufacturers to reimburse Part D sponsors promptly because it is the manufacturers that are financially responsible for payment of applicable discounts. Given this structure, we proposed to codify this requirement at § 423.2315(b)(3). We further proposed in § 423.2315(b)(10) to require that manufacturers pay the quarterly invoices to accounts established by Part D sponsors via electronic funds transfer, unless otherwise specified by CMS, and within 5 business days of the transfer provide the TPA with electronic documentation of payment in a manner specified by CMS. We believe these requirements are appropriate because they provide sufficient time for manufacturers to process the information in order to make the payments and are generally consistent with manufacturer obligations under the Medicaid Drug Rebate Program. Moreover, § 423.2315(b)(2) would prohibit manufacturers from withholding discount payments for their applicable drugs pending dispute resolution and, therefore, the 38-day requirement applies even if the manufacturer decides to dispute discount payments. As noted in our May 21, 2010 guidance, we believe this requirement is necessary to ensure that the manufacturer discounts are paid to Part D sponsors in a timely manner and are not delayed due to disputed amounts. We address our proposals with respect to manufacturers' disputes later in this section of the final rule with comment period.

Section 1860D–14A(b)(2) of the Act requires each manufacturer with an executed Discount Program Agreement in effect to collect and have available appropriate data, as determined by CMS, to ensure that it can demonstrate to CMS compliance with the requirements under the Discount Program. In § 423.2315(b)(5), we would codify this requirement by specifying that such information would include data related to manufacturer labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices and any other data we determine are necessary to carry out the Discount Program. In addition, manufacturers must collect, have available and maintain such information for a period of not less than 10 years from the date of payment of the invoice. The minimum 10-year retention requirement aligns with the standard Part D record retention requirement for Part D sponsors, thereby ensuring that applicable information would be maintained by manufacturers for the same time period.

Section 423.2315(b)(6) would require manufacturers to comply with the audit and the dispute resolution requirements proposed in § 423.2330, which are discussed in section II.A.1.g. of this final rule with comment period.

Section 1860D–43(a)(3) of the Act requires manufacturers to enter into and have in effect, under terms and conditions specified by CMS, a contract with a third party that CMS contracted with under subsection (d)(3) of section 1860D–14A of the Act. We proposed to codify this requirement in § 423.2315(b)(9) by requiring the manufacturer to enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract under section 1860D–14A(d)(3) of the Act.

Finally, proposed § 423.2315(b)(11) would restrict the use of information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute such that the manufacturer could use such information only for purposes of paying the discount under the Discount Program. This means that manufacturers would be allowed to use the information only as necessary to evaluate the accuracy of invoiced discounts and resolve disputes concerning the manufacturer's payment obligations under the Discount Program. We believe this is an important limitation because we are making claim-level detail available to manufacturers that is not otherwise available to the public and therefore, should not be used for reasons beyond which it is being made available. As specified in the Data Use Provisions in Exhibit C of the Discount Program Agreement, the manufacturer would be prohibited from using the information to perform any functions not governed by the Discount Program Agreement, including, but not limited to, determination of non-Coverage Gap Discount payments to Part D sponsors and their subcontractors, payments to other providers of health and drug benefits under any Federal health care program or for marketing activities. Nevertheless, we recognize that manufacturers need to account for the discounts for financial statement forecasting and accounting purposes and therefore, these restrictions would not apply to the use of aggregated, summary-level data (that is, not prescription or claim-level data) for such purposes.

(2) Timing and Length of Agreement

Section 1860D–14A(b)(1)(C) of the Act states that in order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than 30 days after the date of establishment of a model agreement. It also states that for 2012 and subsequent years the manufacturer shall enter into such agreement (or such agreement shall be renewed) not later than January 30 of the preceding year. We proposed to codify these requirements in § 423.23.15(c)(1) and (c)(2).

Section 1860D–14A(b)(4)(A) of the Act also states that an agreement shall be effective for an initial period of not less than 18 months and shall automatically be renewed for a period of not less than 1 year unless terminated under section 1860D–14A(b)(4)(B) of the Act. To ensure that the end of the initial term of each Discount Program Agreement corresponds to the end of a calendar year, § 423.2315(c)(3) would specify that all Discount Program Agreements have an initial period of 24 months, with automatic renewal for a period of 1 year each January 1 thereafter, unless the agreement is terminated in accordance with § 423.2345.

Comment: A commenter requested that CMS clearly state that the Discount Program Agreement cannot be modified through rulemaking. The commenter argued that the Discount Program Agreement predates the regulations and already states, ''the Manufacturer's full compliance with the responsibilities listed * * * in Section II shall constitute satisfaction of the Manufacturer's responsibilities under the Discount Program.'' They point out that the proposed rule generally tracks the manufacturers obligations set forth in the Discount Program Agreement but are not identical in a number of ways. The commenter recommended that CMS reaffirm that manufacturers' obligations are limited to those listed in Section II of the Discount Program Agreement.

Response: We disagree with the commenter that we cannot modify the Discount Program Agreement through rulemaking. The Affordable Care Act required us to establish a model Discount Program Agreement, in consultation with manufacturers, and allow for comment on such model agreement. Section IX (g) of the model agreement specifies that CMS retains the authority to amend the model agreement after consulting with manufacturers and allowing for comment on such amendments. While formal rulemaking is not the only mechanism for consulting with manufacturers, we believe the notice and comment rulemaking process clearly meets the requirement for consultation with manufacturers and allowing for comment.

In some instances we proposed new requirements. For example, we proposed to amend the Discount Program Agreement by adding a requirement that manufacturers maintain up-to-date NDC listings with the electronic database vendors for which manufacturers provide NDCs for pharmacy claims processing. In other instances, the proposed language was intended to mirror the current model Discount Program Agreement requirement even if the language is not identical. We will review the language in the model Discount Program Agreement and make conforming changes if we believe it is necessary to remove any ambiguity between the regulation and the model agreement. This is consistent with our approach to amending Medicare Part C/D agreements with Part D sponsors whereby we generally codify requirements and amend the agreements during the next contracting cycle, which in this case will be for calendar year 2014. Nevertheless, these codified requirements become effective 60 days after the date of publication of this final rule with comment period in the **Federal Register**. Finally, we stated in the proposed rule that we were not codifying all of the provisions in the model Discount Program Agreement; we therefore do not intend to make further changes to any such provisions without first consulting with the manufacturers.

Comment: A few commenters supported our proposal to codify the requirement that manufacturers electronically list and maintain up-to-date electronic listings of all national drug codes (NDCs) of the manufacturer, including the timely removal of discontinued NDCs, in the FDA NDC Directory. These commenters also supported our proposal to require manufacturers to maintain up-to-date NDC listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. However, these commenters do not believe our proposal goes far enough because it does not specify that the manufacturer must ensure their listings are accurate and therefore recommend that we impose monetary penalties and sanctions on manufacturers for inaccurate or out-of-date information.

Response: We believe that manufacturers are already required to provide the FDA with accurate information. We continue to work with the FDA on improving the availability of Part D drug information and could potentially implement additional prescription drug event (PDE) measures in the future to ensure that we only accept PDEs with NDCs that represent currently marketed drug products. We do not believe we have the authority under the Discount Program to impose monetary penalties on manufacturers for inaccurate or out-of-date information listed with the FDA, but we will consider other compliance actions against manufacturers that fail to fulfill their obligations under the Discount Program Agreement.

Comment: A commenter requested that we clarify what information proposed in § 423.2315(b)(5) would be required of manufacturers to maintain regarding FDA approval and NDC Directory listing information for 10 years. Specifically, this commenter noted that these two categories are specified in preamble but are not specified in the regulatory text or Discount Program Agreement. Moreover, the commenter requests that we further specify precisely what data CMS believes should be collected, kept available, and maintained by providing illustrative examples.

Response: We specified the FDA approval and NDC Directory listing information in the preamble to help clarify what data related to manufacturer labeler codes needs to be collected, kept available, and maintained. However, for further clarity we will specify these categories in the regulatory text. We also clarify that pertinent NDC expiration dates refers to last lot expiration dates and have made this change to the regulation text. We do not have other examples that further specify the data manufacturers must collect, keep available, and maintain except to specify that such data should include any information that would be useful to either dispute or support a manufacturer's obligation to pay discounts for its applicable drug products under the Discount Program.

Comment: Many commenters raised concerns with the requirement that a manufacturer must sign a Discount Program Agreement by January 30th of the preceding year because it could result in new drugs being unavailable under Medicare Part D for almost 2 years if this deadline is missed. They point out that some manufacturers may not have been aware of the deadline because they previously did not manufacture any applicable drugs. These commenters recommend that we consider additional measures, such as allowing manufacturers to enter into provisional agreements to join the Discount Program pending FDA approval of a new drug so there would not be a waiting period before the drug could be covered. In addition, these commenters urge CMS to establish a process for using its authority under section 1860D–43(c) of the Act to allow coverage for Part D drugs not covered under agreements if we determine that a drug is ''essential to the health of beneficiaries.''

Response: We appreciate the concerns raised by commenters that new drugs manufactured by companies without existing Discount Program Agreements could be excluded from Medicare Part D until the next opportunity to enter into the Discount Program. However, the deadline of January 30th of the preceding year is a statutory deadline. But we already allow, and encourage, manufacturers without drug products currently on the market to sign Discount Program Agreements in advance so that there would be no waiting period if they do begin marketing an applicable drug; a number of companies have done so. We are also aware that some manufacturers have been successful in working out licensing arrangements with other manufacturers that have existing Discount Program Agreements to temporarily include drug products under such existing agreements and avoid any delay in access under Part D. Based on the current level of participation by manufacturers and the breadth of applicable drugs covered by Discount Program Agreements, we do not believe it is necessary at this time to establish a detailed process for using our authority under section 1860D–43(c) of the Act to allow coverage for applicable drugs not covered by Discount Program Agreements.

After consideration of the public comments received, we are finalizing the proposals in this section with two modifications. We added FDA drug approval data and FDA NDC Directory listing data to the required information in § 423.2315(b)(5) and clarified in § 423.2315(b)(5) that pertinent NDC expiration dates refers to NDC last lot expiration dates.

e. Payment Processes for Part D Sponsors (§ 423.2320)

We are finalizing our October 11, 2011 proposed rule to provide monthly interim coverage gap payments to Part D sponsors in § 423.2320(a). The interim payments ensure that Part D sponsors will have the funds available to advance the manufacturer discounts to applicable beneficiaries at the point of sale. We also proposed, and are now finalizing, a process to reconcile the estimated interim coverage gap discount payments with actual Discount Program costs in § 423.2320(b). Coverage Gap Discount Reconciliation will occur after Part D payment reconciliation.

Comment: A number of commenters raised the issue of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap. One requested that CMS clarify plan sponsor responsibility in the gap for applicable drugs. Others noted that the definition of negotiated price is not the same in the coverage gap as it is in the other phases because it excludes the dispensing fee. Commenters noted that if beneficiaries must pay dispensing fees and vaccine administration fees for brand drugs in the gap, this would increase their out-of-pocket costs.

Response: We issued proposed guidance on Part D plan sponsor liability for dispensing and vaccine administration fees in the Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter, which was published on February 17, 2012. Based on comments received in response to the Advance Notice, we will finalize a policy in the Final Rate Announcement.

f. Provision of Applicable Discounts (§ 423.2325)

(1) Obligations of Part D Sponsors; Provision of Point-of-Sale Discounts

Section 1860D–14A(c)(1)(A)(ii) of the Act requires the manufacturer discounts to be provided to beneficiaries at the point-of-sale. As discussed previously in this subpart, manufacturer discounts can be provided at point-of-sale only if the entity adjudicating the electronic pharmacy claim has the information necessary to determine at that point in time: (1) The drug is an applicable drug; (2) the beneficiary is an applicable beneficiary; (3) the claim is wholly or partly in the coverage gap; and (4) the amount of the discount, taking into consideration Part D supplemental benefits that pay first. Working with industry experts on electronic transactions, we have determined that the only entity capable of providing the discount at point-of-sale is the Part D sponsor because no other entity would have all four pieces of information at that time. Therefore, § 423.2325(a) would require Part D sponsors to provide applicable beneficiaries with applicable discounts on applicable drugs at point-of-sale on behalf of the manufacturer. Part D sponsors would be required by § 423.2325(b)(1) to determine that: (1) an enrollee is an applicable beneficiary (as defined in § 423. 100); (2) a Part D drug is an applicable drug (as defined in § 423.100); and (3) the amount of the applicable discount (as defined in § 423.2305) in order to provide a discount at point-of-sale.

Part D sponsors would use the date of dispensing for purposes of providing an applicable discount at point-of-sale and determining the amount of such discount. However, if later information changes the beneficiary's eligibility for the applicable discount back to the date of dispensing (for example, retroactive low-income subsidy status changes, or retroactive changes resulting from automated TrOOP balance transfers between Part D sponsors via Financial Information Reporting (FIR) transactions), or changes the amount of the applicable discount or the applicable beneficiary's cost sharing, we proposed to require, in § 423.2325(b)(2), that Part D sponsors make retroactive adjustments to the applicable discount as necessary to reflect such changes. For example, if a claim for an applicable drug was originally adjudicated in the initial coverage phase but later moved into the coverage gap as a result of receipt of an automated TrOOP balance transfer amount from a previous Part D sponsor, the applicable discount and the corrected beneficiary cost-sharing would be reported on the adjusted PDE. Conversely, if an original claim was adjudicated in the coverage gap with an applicable discount but is later reprocessed in the catastrophic phase as a result of the receipt of an automated TrOOP balance transfer amount, the applicable discount reported on the adjusted PDE is the mechanism for refunding the manufacturer.

If an applicable beneficiary has a claim for an applicable drug that straddles the coverage gap and another phase of the Part D benefit, section 1860D14A-(g)(4)(C) of the Act requires that Part D sponsors only provide the discount on the portion of the negotiated price of the applicable drug that falls at or above the initial coverage limit (ICL) and below the annual out-of-pocket threshold. Because our proposed definition of negotiated price for purposes of the Discount Program would exclude both the dispensing fee and vaccine administration fee, proposed § 423.2325(b)(3) would have required the dispensing fee and vaccine administration fee be included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold, to the extent possible (that is, as much of the dispensing fee that can be included in the portion below the ICL or above the annual out-of-pocket threshold). However, as discussed later, we are not finalizing this proposal at § 423.2325(b)(3).

Section 423.2325(b)(4) would require Part D sponsors to first determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and then notify such beneficiaries. This situation could occur if participating manufacturers fail to timely notify CMS when a new labeler code becomes available or otherwise fail to provide us with all of their labeler codes as required.

In § 423.2325(c) we proposed to require that Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. We do not believe the point-of-sale requirement was intended to exclude discount payments for claims that were not adjudicated by the Part D sponsor at point-of-sale: even though the statute requires provision of the discount at the point-of-sale, it does not state that applicable beneficiaries are not entitled to the discount if it was not provided at the point-of-sale. Instead, we believe this requirement was meant to ensure the discount would be available at the point-of-sale when and if a claim is electronically adjudicated. Therefore, beneficiaries would still receive the discount in the limited circumstances when they submit claims for reimbursement that were not adjudicated at the point-of-sale, such as when they needed to obtain a prescription from an out-of-network pharmacy or on an emergency basis.

(2) Collection of Data

Section 1860D–14A(c)(1)(C) of the Act states that we may collect appropriate data from Part D sponsors in a timeframe that allows for applicable discounts to be provided for applicable drugs. Section 423.2325(d) of the proposed rule would require Part D sponsors to provide CMS with appropriate data on the applicable discount provided by the Part D sponsors in a manner specified by CMS. In implementing the Discount Program we determined that using the existing PDE reporting process to collect the necessary data would be most efficient and least burdensome for Part D sponsors. Thus, we would require Part D sponsors to report the applicable discount that was provided at the point-of-sale as part of the PDE record in addition to the other claim-level detail that is reported on the PDE. We would also require Part D sponsors to report confirmation of payment from manufacturers during the quarterly invoice process.

(3) Other Health or Prescription Drug Coverage

Section 1860D–14A(c)(1)(A)(v) of the Act requires that applicable discounts for applicable drugs get applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify. We proposed to codify the requirement in § 423.2325(f) by specifying that an applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied. Since the Part D sponsor would provide the discount at the same time as it makes primary payment on the claim, this coordination generally would take place in real time as the claim is adjudicated by the pharmacy in accordance with existing Part D coordination of benefit requirements. We specify that this requirement would not apply to Medicare secondary payer claims because the beneficiary would not have a Medicare Part D coverage gap on the initial claim to the primary payer. However, this requirement would apply to coordination of benefit claims in which the Part D sponsor coordinates benefits post point-of-sale with another payer who paid primary in error and reimburses that payer and/or the beneficiary for amounts that the plan would have paid as the primary payer.

(4) Supplemental Benefits

Section 1860D–14A(c)(2) of the Act provides that if an applicable beneficiary has supplemental benefits under his or her Part D plan, the applicable discounts shall not be provided until after such supplemental benefits have been applied. Supplemental benefits offered under a Part D plan would have the meaning set forth in § 423.100 (see discussion of supplemental benefits under the proposed definition ‘‘other health or prescription drug coverage’’). Section 423.2325(e)(1) would codify this requirement by specifying that an applicable discount is applied to beneficiary cost-sharing after supplemental benefits have been applied to the claim for an applicable drug, and paragraph (e)(2) would establish that no applicable discount is available if supplemental benefits eliminate the coverage gap so that a beneficiary has zero cost-sharing on a claim.

If a Part D sponsor offers an individual market plan with supplemental benefits on applicable drugs covered between the plan's initial coverage limit and the Medicare Part D catastrophic threshold using either coinsurance or fixed copay, the value of the supplemental benefits would need to be calculated first on any claim for an applicable drug as the difference between the proposed supplemental cost-sharing and the coinsurance under the basic benefit. For example, if the supplemental benefit for an applicable drug had a 60 percent coinsurance, the value of the supplemental benefits that would need to be applied first (plan liability) would be 40 percent (100 percent coinsurance under basic minus 60 percent coinsurance) of the negotiated price of the drug. The applicable discount would then be calculated as 50 percent of the negotiated price (as defined in § 423.2305) less the supplemental benefit. Beneficiary cost-sharing would then be the remainder of the negotiated price after the plan liability and applicable discount had been applied. Thus, in the case of either a coinsurance or copay design for supplemental benefits, the amount the beneficiary pays at point-of-sale would generally be approximately 50 percent of his or her expected cost-sharing under the plan's benefit package. This amount will change over time as the coinsurance level in the basic benefit for a beneficiary is reduced until it reaches 25 percent in 2020. Proposed § 423.2325(e)(3) would have required that the dispensing fee and the vaccine administration fee be included in the Part D sponsor liability portion of a claim with supplemental benefits. For the same reasons that we proposed to require the dispensing fee and the vaccine administration fee to be applied to the portion of a claim for an applicable drug that falls below the initial coverage limit or above the annual out-of-pocket threshold, to the extent possible, on straddle claims, we believed that including the dispensing fee and the vaccine administration fee in the plan liability supports the statutory goal of alleviating the burden of the coverage gap on applicable beneficiaries.

(5) Pharmacy Prompt Payment

Section 1860D–14A(c)(1)(A)(iv) of the Act requires procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between: (1) the negotiated price of the applicable drug; and (2) the discounted price of the applicable drug. This amount would be equal to the amount of the applicable discount. The applicable number of calendar days with respect to claims for reimbursement submitted electronically is 14 days, and otherwise, is 30 days. We proposed to implement this requirement in § 423.2325(g) by specifying that Part D sponsors reimburse a pharmacy or mail order service the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing an applicable drug. This requirement would apply to all network pharmacies, including but not limited to long term care pharmacies and home infusion pharmacies.

Finally, we proposed to add a new paragraph (24) to § 423.505(b) so that the requirements we are proposing in § 423.2325 are included in all Part D sponsor contracts with us.

Comment: A commenter requested that CMS clearly indicate how Part D sponsors implement the plan responsibility for reduced cost-sharing in the coverage gap beginning in 2013 when the phase-down of coverage gap brand drug cost-sharing will begin to take effect.

Response: We agree that additional clarification is necessary to explain how plans need to determine both plan and beneficiary liabilities for brand-name drug coverage when the additional brand-name coverage in the coverage gap begins to phase in starting in 2013, but this is beyond the scope of this regulation. We addressed the issue in the 2013 Advance Notice by clarifying how manufacturer, beneficiary, and Part D sponsor liabilities, including dispensing fee liabilities, for coverage gap claims must be determined beginning in 2013. In light of that guidance, we will not be finalizing the requirements in proposed § 423.2325(b)(3) and (e)(5) with respect to dispensing and vaccine administration fees, and have re-designated proposed § 423.2325(b)(4) as § 423.2325(b)(3) in the final rule.

Comment: A few commenters opposed the requirement under proposed § 423.2325(b)(4) (redesignated as § 423.2325(b)(3)) that would require Part D sponsors to notify affected beneficiaries whenever CMS specifies a retroactive effective date for a labeler code. They contend that such notice will be less likely to be beneficial to the beneficiary as the Discount Program matures. They also believe it often will be difficult for the Part D sponsor to accurately identify if an alternative product had been prescribed and covered after the initial denial and thus Part D sponsors will cause more enrollee confusion by ''over notifying'' enrollees.

Response: We disagree with the commenters. We do not believe manufacturers should be excused from their obligation to pay a discount because they failed to timely report a labeler code for an applicable drug to CMS. Moreover, and more importantly, we do not believe the administrative burden on Part D sponsors, which we do not anticipate will be significant, justifies denying a beneficiary access to a discount for which they are entitled. As discussed in the proposed rule, Part D sponsors can minimize any beneficiary confusion by notifying only those beneficiaries that it determines likely still need the drug or who paid for the drug out-of-pocket.

Comment: A commenter recommended that we require that the discount payment be calculated before any Part D supplemental benefits are applied by a Part D plan.

Response: The requirement proposed under § 423.2325(e) is consistent with the statutory requirement under section 1860D–14A(c)(2) of the Act. We do not have the authority to change the statutory requirement to require the discount payment to be calculated before Part D supplemental benefits are applied by a Part D plan.

Comment: Several commenters supported our proposal to implement the pharmacy reimbursement requirements of section 1860D–14A(c)(1)(A)(iv) of the Act by specifying that Part D sponsors reimburse a pharmacy or mail order service the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing an applicable drug. The applicable number of calendar days with respect to claims for reimbursement submitted electronically is 14 days, and otherwise, is 30 days. We proposed that this requirement would apply to all network pharmacies including but not limited to long-term care and home infusion pharmacies. Other commenters recommended that we reconsider applying this requirement to long-term care and home infusion pharmacies because current billing practices in these pharmacy settings, such as once a month billing practices, could result in Part D sponsors being out of compliance with the requirements.

Response: We acknowledge that current billing practices in long-term care and home infusion pharmacies could prevent Part D sponsors from complying with this provision if they are not billed by the pharmacy on the date of service. Therefore, we clarify in § 423.2325(g) that for long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement and not the actual date the pharmacy dispensed the medication. After consideration of the public comments received, we are with the exception of the provisions at § 423.2325(b)(3) and (e)(3) finalizing the policies in this section with modification to § 423.2325(g). We note that we are not finalizing the proposed provisions for § 423.2325(b)(3) and (e)(3) and have redesignated proposed § 423.2325(b)(4) as § 423.2325(b)(3) in the final rule.

g. Manufacturer Discount Payment Audit and Dispute Resolution (§ 423.2330)

(1) Third Party Administrator Audits

Section 1860D–14A (d)(3)(D) of the Act permits manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the TPA to determine discounts for applicable drugs of the manufacturer under the Discount Program. Section 423.2330(a) would codify the provisions of the Discount Program Agreement governing these audits by specifying the requirements for requesting an audit and the rights of manufacturers associated with conducting audits.

We proposed in § 423.2330(a)(1) that the term periodic be defined as no more often than annually. We believe that this standard would ensure that all manufacturers have an opportunity to conduct meaningful audits within available TPA resources. The proposed definition of periodic represents a balance between frequent audits that may provide the greatest level of detail and very infrequent audits that may be less costly to implement, but may not provide needed information in a timely manner.

Section 1860D–14A(d)(3)(D) of the Act requires that our contract with the TPA permit audits by manufacturers of the data and information used by the TPA to determine discounts for manufacturer's applicable drugs. Because the statute thus permits the manufacturer to audit data used by the TPA, and importantly, does not grant manufacturers a right to audit CMS or the Part D sponsors, we proposed to specify in regulations that the audit right is limited to information held by the TPA and used to calculate discounts. This means that the manufacturer would not have the ability to audit CMS records or the records of Part D sponsors. We believe the data provided from the TPA provides manufacturers with appropriate and sufficient information to conduct an audit because it provides the claim-level information specified in the Discount Program Agreement that is used to calculate the discounts. We believe that defining the data available for audit also requires balancing considerations between efficiently administering the Discount Program and providing manufacturers with an appropriate level of information to validate invoices. Section 423.2330(a)(3) would establish, consistent with the Discount Program Agreement, that manufacturers may audit a statistically significant sample of the database used by the TPA to calculate gap discounts. We believe that a statistically significant sample provides a balance between allowing an audit to include: (1) All of the data, which would provide complete information, but would be unwieldy in terms of resources; and (2) a very small sample that would have insufficient information but be inexpensive to implement. Moreover, the use of a statistically valid sample meets generally accepted auditing standards, would provide sufficient data to manufacturers to reach statistically valid conclusions that could be used to dispute discount payments, and is an efficient use of audit resources.

Proposed § 423.2330(a)(3) also supports our obligation to protect the privacy of beneficiary medical information. This section proposed that, with the exception of work papers, audit data may not leave the room where the audit is conducted, which would further protect beneficiary privacy. Another measure to protect the confidentiality of beneficiary medical information is contained in proposed § 423.2330(a)(4), which would specify that the auditor may only release an opinion of the results of the audit and may not release any other information obtained from the audit, including its work papers, to its client, employer, or any other party. We believe these limitations on the distribution of data support beneficiary privacy, while addressing manufacturer need for access to data that are relevant to the calculation of the gap discounts. These regulations all would codify provisions in the current Discount Program Agreement.

(2) Manufacturer Audits

Section 1860D–14A(e)(1) of the Act specifies that each manufacturer with a Discount Program Agreement in effect shall be subject to periodic audit by CMS and we proposed to codify this requirement in § 423.2330(b). Similar to the limitation in § 423.2330(a)(1), we proposed to define the term periodic in § 423.2330(b)(1) as no more often than annually. In § 423.2330(b)(3) we proposed that we would have the right to audit appropriate data of the manufacturer, including data related to a manufacturer's FDA-assigned labeler codes, expiration date of NDCs, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, as well as any other data CMS determines are necessary to carry out the Discount Program.

(3) Dispute Resolution

Section 1860D–14A(c)(1)(A)(vii) of the Act requires the Secretary to establish ''a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract * * *.''

Therefore, we proposed in § 423.2330(c) a multistage dispute resolution process consisting of: (1) An initial dispute stage; (2) an appeals stage for manufacturers that do not accept the findings of the dispute process; and (3) a final administrator review when either a manufacturer or CMS disagrees with the outcome of the initial appeals process.

Section 423.2330(c) would include a timetable for the three-stage approach to manage the process most efficiently and to support equal treatment of each appeal. The timetable ensures that manufacturers' disputes are resolved as quickly as possible, while allowing both parties to perform the necessary calculations and investigations to evaluate the gap discount invoice. The proposed timeframes were established by estimating the time required to analyze the data presented, by the volume of claims, and by considering the characteristics of the Discount Program compared to the other similar programs previously noted.

Specifically, we proposed in § 423.2330(c)(1) that manufacturers may dispute quarterly gap discount amounts by providing notice of the dispute to the TPA within 60 days of the receipt of information that is the subject of the dispute. The information is limited to data received from the TPA, or as a result of a manufacturer's audit.

Proposed § 423.2330(c)(2) also states that the notice of dispute be accompanied by supporting evidence that is material, specific, and related to the dispute. We proposed this requirement because the manufacturer bears the burden of proof that the PDE data is incorrect. We also proposed in § 423.2330(c)(3) to codify the Discount Program Agreement provision that manufacturers may not withhold any invoiced amounts pending dispute resolution except for invoiced amounts for applicable drugs without labeler codes provided by the manufacturer to us. The proposition to generally bar the withholding of disputed invoice amounts is justified because gap discounts are owed by manufacturers but are paid by Part D sponsors to beneficiaries at the point-of-sale; we believe that the prohibition of withholding disputed invoices will minimize the risk to Part D sponsors for these discount-related incurred liabilities without significantly increasing the financial risk to a manufacturer because of the extensive quality assurance CMS performs on PDEs submitted by Part D sponsors. The PDE data used to calculate quarterly invoices are of high quality. The PDE data are derived from claims for each prescription submitted to Part D sponsors for payment. Part D sponsors validate each claim to comply with the False Claims Act and as part of their process to reimburse pharmacies for the cost of the drug. In addition, we implement multiple edits to validate the PDE data submitted by Part D sponsors. Those edits include identification and adjustment of outlier and other inappropriate entries for variables such as discount amount, beneficiary eligibility for the gap discount, incorrect NDCs, etc. Therefore, the burden of proof is on manufacturers to demonstrate that the data used to calculate the quarterly invoice are incorrect.

Section 423.2330(c)(4) would allow manufacturers to request an additional adjudication by the Independent Review Entity (IRE), under contract with CMS, within 30 days of the receipt of an unfavorable determination from the TPA, or if no decision was received from the TPA, within 90 days of the receipt of the dispute submission. This section also proposed that the IRE be required to make a determination within ninety calendar days of receipt of the manufacturer request for an appeal.

Section 423.2330(c)(6) establishes a final administrative step to support an equitable dispute resolution process. We proposed that both manufacturers and CMS would have the right to request a final review of the dispute by the Administrator. Since we administer the Discount Program and manufacturers have financial liability for the discounts, both parties have an interest in ensuring an equitable resolution to the dispute. We proposed that this request be made within 30 days after the manufacturer receives a decision from the IRE to facilitate a timely outcome. Finally, we proposed that the decision of the Administrator would be final and binding.

We proposed to codify the policies as described and welcomed comments on the dispute and appeals process.

Comment: A few commenters recommended that we include affected Part D sponsors in the disputes and appeals process, and that Part D sponsors be given appeal rights if disputes or appeals are upheld.

Response: We do not believe it is necessary, nor would it be helpful, to insert Part D sponsors in every step of every manufacturer dispute and appeal. This process is specifically designed to address manufacturer disputes or appeals and manufacturers have the burden to demonstrate that an applicable discount advanced by the Part D sponsor likely is in error according to standards established in CMS guidance. If the manufacturer satisfies the threshold, the Part D sponsor will be given the opportunity to confirm the accuracy of the discount and if confirmed, the dispute or appeal will be denied. If the manufacturer dispute or appeal does not meet the standard for demonstrating likely error in the first place, the dispute or appeal will be denied without needing Part D sponsor confirmation. In situations that involve the determination of applicable drug status for an NDC based upon its FDA approval status, CMS will make those determinations based upon the information that was available from the FDA on the date of dispensing. While Part D sponsors will not have the opportunity to appeal determinations that uphold manufacturer disputes or appeals under this process, Part D sponsors have appeal rights under the Part D payment reconciliation process to redress payment disputes, including those related to the Discount Program.

After consideration of the public comments received, we are finalizing the policies in this section without modification.

h. Beneficiary Dispute Resolution (§ 423.2335)

Section 1860D–14A(c)(1)(A)(vii) of the Act requires CMS to provide a reasonable dispute mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the TPA. While § 423.2330(c) would address the disputes that could arise between the manufacturer and CMS or the TPA, § 423.2335 would provide the beneficiary dispute resolution requirements. Specifically, § 423.2335 would provide that beneficiaries shall have access to the Part D coverage determination and appeals process as described in § 423.558 through § 423.638 for disputes involving the availability and amount of applicable discounts under the Discount Program.

Comment: Some commenters supported CMS' proposal in § 423.2335 to provide beneficiaries with access to the existing Part D coverage determination and appeals process as described in §§ 423.558 and 423.638 for disputes involving the availability and amount of applicable discounts under the Discount Program. However, a commenter raised concerns that the existing process is not well understood by beneficiaries and therefore we should require Part D plans to provide explicit, plain language information on how to file a dispute.

Response: We agree with commenters that supported our proposal. The existing Part D coverage determination and appeals process provides the best and most efficient mechanism for resolving beneficiary disputes involving the availability and amount of applicable discounts. We do not believe it would be beneficial to anyone, most importantly beneficiaries, to establish an entirely separate and duplicative process. Moreover, we do not believe a new plain language requirement is necessary because Part D plans are already required to use a consumer tested model Evidence of Coverage (EOC) that is intended to explain the existing Part D coverage determination and appeals process in language that is appropriate for beneficiaries.

After consideration of the public comments received, we are finalizing the policies in this section without modification.

i. Compliance Monitoring and Civil Money Penalties (§ 423.2340)

Section 1860D–14A(e)(2) of the Act requires us to impose a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement. The statute sets forth the formula for determining the CMP amount, which will equal the sum of the amount that the manufacturer would have paid with respect to such discounts under the agreement (which will then be used to pay the discounts which the manufacturer had failed to provide) plus 25 percent of such amount. Section 423.2340 would implement these requirements and establish the procedures for imposing and collecting the CMPs in accordance with subpart T of this part. Accordingly, we proposed to revise the definition of ''affected party'' in subpart T (as defined in § 423.1002) by adding the term ''manufacturer'' (as defined in § 423.2305) to the definition and clarifying that we interpret the use of ''Part D sponsor'' throughout subpart T to be synonymous with ''affected party''. In accordance with the Discount Program Agreement and proposed § 423.2315(b)(3), manufacturers must pay each Part D sponsor within 38 calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice except as specified in § 423.2330(c)(3). Therefore, we consider a manufacturer to have failed to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement if it fails to comply with this requirement unless such failure is due to technical or other reasons beyond the control of the manufacturer, such as a natural disaster. Consequently, we would impose a civil money penalty whenever a manufacturer fails to make full payment on its invoice within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discount included on the invoice unless such failure is due to technical or other reasons beyond the control of the manufacturer. We plan to add this provision to the Discount Program Agreement.

Section 423.2340(c) codifies the methodology for determining the amount of the CMP as equal to the amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide, plus 25 percent of such amount. This amount may be reduced by any amount that the manufacturer has paid after the 38th calendar day but before the date the CMP is collected. We interpret this to mean that the CMP would be calculated based upon the outstanding invoiced amount that was not paid within 38 calendar days of receipt as required under the Discount Program Agreement and proposed § 423.2315(b)(3) irrespective of any partial or late payments. In other words, a manufacturer's failure to pay the entire invoice amount would trigger the CMP and late payments would not relieve the manufacturer of its obligation to pay an additional 25 percent of the unpaid amount from the invoice. In order to ensure consistency and transparency with the imposition of these civil money penalties, unless the exception applies (that is, the payment is late due to technical or other reasons beyond the control of the manufacturer), we would impose the additional 25 percent on all invoiced amounts not paid within 38 calendar days of receipt, even, for example, if the payment is only 1 day late.

Section 423.2340(d) specifies that if CMS makes a determination to impose a CMP, we would send a written notice of our decision to impose a CMP that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing (as specified under § 423.1006) and information about where to file the request for hearing. To ensure a consistent approach to CMPs, we proposed extending existing appeal procedures for CMPs in subpart T of this part to manufacturers appealing a CMP imposed under the Discount Program. We have utilized this appeals process for more than 20 years for various types of adverse agency determinations affecting an array of medical providers, MA organizations, and Part D sponsors.

We therefore proposed to use this well established process and infrastructure for CMP appeals from manufacturers that have contracted with the Discount Program and are delinquent in paying the discounts as required. To that end, we proposed to revise the definition of ''affected party'' in § 423.1002 to include manufacturers participating in the Discount Program. Section 423.2340(e) would provide that we would initiate collection of the CMP following expiration of the timeframe for requesting an ALJ hearing, which is 60 calendar days from the CMP determination, as specified in § 423.1020 if the manufacturer did not request a hearing; and CMS would initiate collection of the CMP once the administrative decision is final if a manufacturer requests a hearing and our decision to impose the CMP is upheld.

Section 1860D–14A(e)(2)(B) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to CMPs under this subpart to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act. We proposed to codify this requirement in § 423.2340(f). We welcomed comments on this proposal. We did not receive any comments and we are finalizing these provisions as proposed.

j. Termination of Agreement (§ 423.2345)

Section 1860D–14A(b)(4)(B)(i) of the Act provides that we may terminate a Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and CMS shall provide, upon request, a hearing concerning such termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate. Section 423.2345 would codify these requirements consistent with the termination provisions in the Discount Program Agreement. For instance, § 423.2345(a)(1) would clarify that ''good cause shown'' must relate to the manufacturer's participation in the Discount Program. Our proposed regulation would further specify that we must provide the manufacturer with an opportunity to cure any ground for termination within 30 calendar days of receipt of the written termination notice. In addition, we proposed, consistent with the statutory requirement as reflected in the Discount Program Agreement, that the manufacturer may request a hearing with a hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination, and such hearing must take place prior to the effective date of termination with sufficient time for such effective date to be repealed if we determine appropriate.

In order to address potential timing issues with appeals during the termination process, we proposed to clarify in § 423.2345(a)(2) that termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section. Proposed paragraphs (a)(4) and (5) state, in part, that CMS will provide a manufacturer with a hearing before the hearing officer about such termination if requested in writing within 15 calendar days of receiving notice of the termination. Further, CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. Therefore, a termination would not be effective until either the timeframes to pursue a hearing with the hearing officer or CMS Administrator have passed or a final decision has been issued by the hearing officer or CMS Administrator and there is no remaining opportunity to request further review.

We also proposed in § 423.2345(a)(5)(i) to specify that CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. The Discount Program Agreement currently provides only that a manufacturer may request review of an unfavorable decision by the CMS Administrator. However, we believe that a fair appeals process must ensure that both parties have an opportunity for further review of a decision made by hearing officer. The decision of the CMS Administrator would be final and binding on either party. We requested comments on these termination requirements.

Section 1860D–14A(b)(4)(B)(ii) of the Act provides that a manufacturer may terminate the Discount Program Agreement for any reason. Such termination shall be effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year. We proposed to codify these requirements in § 423.2345(b).

Section 1860D–14A(b)(4)(B)(iii) of the Act states that any termination shall not affect discounts for applicable drugs of the manufacturer that are due under the Discount Program Agreement before the effective date of the termination and we proposed to codify this requirement in § 423.2345(c). However, upon the effective date of the Discount Program Agreement termination, the manufacturer's drugs would no longer be covered under Medicare Part D. In addition, § 423.2345(d) would specify that we would cease releasing data to the manufacturer except as necessary to ensure the manufacturer reimburses applicable discounts for time periods in which the Discount Program Agreement was in effect and would notify the manufacturer to destroy data files provided by us under the Discount Program Agreement.

Finally, § 423.2345(e) would restrict reinstatement of manufacturers that previously terminated their Discount Program Agreements or had them terminated by CMS to those manufacturers that pay any and all outstanding applicable discounts incurred during any previous periods under Discount Program Agreements.

We did not receive any comments and we are finalizing these provisions as proposed.

2. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs (§ 423.100)

Section 175 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1860D–2(e)(2)(A) of the Act to include barbiturates ''used in the treatment of epilepsy, cancer, or a chronic mental health disorder'' and benzodiazepines. MIPPA further specified that these amendments apply to prescriptions dispensed on or after January 1, 2013. Accordingly, we proposed to revise the definition of a Part D drug at § 423.100 to include barbiturates used for the three specified medical indications and benzodiazepines that are dispensed on or after January 1, 2013. Like any other prescription drugs under the Part D benefit program, barbiturates as specified and benzodiazepines must meet all other conditions for Part D drugs found in § 423.100.

As in the proposed rule, we once again remind sponsors that it is their responsibility to use the tools (that is, system edits, quality assurance checks) at their disposal to ensure barbiturates are covered for the conditions specified in the statute. Also, given the vulnerability of both barbiturates and benzodiazepines to misuse and abuse, it is recommended that Part D sponsors use their drug utilization review tools to identify and prevent waste and clinical abuses/misuses.

Comment: A number of commenters endorsed the statutory inclusion of barbiturates as specified and benzodiazepines as covered Part D drugs. Some of these commenters anticipated that the change would result in better treatment of health conditions such as mental health conditions, with a commenter predicting lowered health care spending would stem from better quality of life and health care outcomes. Several supporters opined that the existing tools in the Part D program were sufficient to, for instance, address misuse and protect beneficiaries from harm.

Response: We appreciate the commenter support of the statutory inclusion of these medications.

Comment: Several commenters suggested that CMS restrict access to the drugs by, for instance, removing the medical indications requirements from the regulation, limiting benzodiazepines coverage to short-acting agents, or allowing barbiturates only for seizure disorders.

Response: We lack the authority to restrict drugs through any of the modifications suggested by these commenters because of the clear statutory mandate found in section 175 of MIPPA, which amends section 1860D–2(e)(2)(A) of the Act to include as Part D drugs both barbiturates used in the ''treatment of epilepsy, cancer, or a chronic mental condition'' and benzodiazepines. Accordingly, our proposed revisions must include as Part D drugs barbiturates for the three medical indications, as well as benzodiazepines.

That we track the statutory language does not, however, mean that there are no restrictions on the availability of barbiturates as specified and benzodiazepines—statutory and regulatory requirements apply to restrict availability. As is the case for all Part D drugs, a barbiturate as specified or a benzodiazepine may only be a Part D drug if it falls within the definition of Part D drug at § 423.100, which would mean that it must—

- Be used for a medically accepted indication;
- Be dispensed only upon a prescription;
- Meet requirements described in section 1927(k)(2)(A)(i) through (iii) of the Act; and
- Not be otherwise excluded from Part D coverage on the basis that payment for such drug, as so prescribed and dispensed or administered to an individual, is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).

Additionally, for any barbiturates as specified or benzodiazepines that meet the definition of an applicable drug under section 1860D–14A(g)(2) of the Act, in order for coverage to be available under Part D, the manufacturers of the brand drug must participate in the Medicare Coverage Gap Discount Program.

Comment: A number of commenters, many of which endorsed the inclusion, voiced concerns with utilization control issues—with the vast majority of these commenters questioning whether the available Part D utilization tools would be effective enough in restricting access to barbiturates for the specified indications and benzodiazepines as to prevent misuse. In contrast, a few commenters voiced concern that CMS is ''encouraging'' plans to apply utilization management tools to therapies for chronic conditions, such as mental illnesses. Stating that utilization management tools had impeded beneficiary access to medications in the past, these commenters requested that CMS remove the language about these tools from the preamble.

Response: We do not agree with the commenters who suggested we remove language from the preamble of the proposed rule that discusses the availability of drug management tools. We see no justification to treat barbiturates and benzodiazepines any differently from how we treat all other Part D drugs.

Comment: Many commenters requested more direction and instructions regarding the use of drug utilization tools. A commenter requested that CMS implement restrictions such as a specific quantity limit per year, while the two commenters requested that CMS provide instructions that would, for instance, prevent step therapy and fail first policies for individuals already on these medications. Several commenters indicated that they wanted to use prior authorization (PA) to ensure that barbiturates would be prescribed only when used in the treatment of epilepsy, cancer, or chronic mental health disorders. A few others indicated that when used for certain indications (for instance, barbiturates for uses listed in the statute and benzodiazepines for epilepsy), barbiturates and benzodiazepines might be part of a protected class—with a commenter stating that in such instances the drugs must be made available to members and another asserting that the drugs must be denied protected class status.

Response: These comments are beyond the scope of the proposed rule. We did not propose to implement any special rules with regard to these drugs; rather, we proposed merely to codify the statutory requirement set forth in section 175 of MIPPA. To the extent we believe additional guidance about these products is necessary or appropriate, we will provide such guidance in the future.

Comment: A commenter requested guidance on the issues as soon as possible, but no later than January 2012, to provide plans enough time for appropriate utilization management as part of the 2013 formulary submissions.

Response: Although this comment is beyond the scope of the proposed rule, we would like to note that we believe our current formulary guidance provides Part D sponsors with the information they need to make such determinations.

Comment: A commenter suggested that the inclusion would impact the accuracy of the current risk adjustment formula because the new drugs would be available only to members with the three specified medical conditions. The commenter accordingly requested that, after January 1, 2013, the risk adjustment factors associated with these specified conditions be increased to reflect the increased costs expected from covering these drugs.

Response: In the calibration of the original Part D risk adjustment model and in subsequent versions, we reasoned that benzodiazepines and barbiturates were substitutable drugs and included the costs of these drugs as a proxy for their substitutes. Given that we never removed either barbiturates or benzodiazepines from our Part D model calibration, the mandated inclusion will not impact the accuracy of the current risk adjustment model. In a discussion in our 2006 Advanced Notice on removing non-covered Part D drugs from the calibration of the risk adjustment, we stated, ''Other non-covered drugs, benzodiazepines and barbiturates, were intentionally left in the file because their costs proxy for the costs of substitutes. This was deemed preferable to removing the claims and costs altogether.'' See Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates, Attachment II, Risk Adjustment Model, page 45.

Comment: A commenter questioned whether CMS had conducted an analysis to determine if all manufacturers of barbiturates and benzodiazepines were currently participating, or would be offered the opportunity to participate in the Coverage Gap Discount Program, because they may have not sought participation when the drugs were excluded.

Response: Given that the Coverage Gap Discount Program only applies to brand drugs and that most barbiturates and benzodiazepines are available as generics, we believe that Part D coverage will be available for most—if not all—types of barbiturates that treat the specified indications and benzodiazepines. Indeed, at this time, we are not aware of any barbiturates as specified or benzodiazepines that will not be covered on the basis that a manufacturer is not participating in the program.

Comment: Several commenters expressed concerns that, because the High Risk Medication (HRM) Part D Plan Rating measure incorporates the Beers list, which identifies benzodiazepines and barbiturates as potentially harmful for the elderly, plan ratings will suffer resulting in lower bonus payments. While a commenter requested that CMS deny Part D coverage of drugs on the Beers list, others requested changes to the rating system itself such as excluding the medications from the HRM measure calculation to give the industry time to understand the impact on the safety of beneficiaries or adjusting the 4-star threshold.

Response: As we noted in our discussion of the Part D High-Risk Medication (HRM) measure in our draft 2013 Call Letter published on February 17, 2012 (page 63), we will continue to explore changes to this measure. Modifications may result from specification changes made by the Pharmacy Quality Alliance (PQA) or National Committee for Quality Assurance (NCQA) as they consider modifying the specifications and medication list based on the American Geriatrics Society's (AGS) update to the Beers List. We will consider applying these updates to future Plan Ratings and changes to the measure medication list will not be retroactively applied for the 2013 Plan Ratings. Rather, we will apply changes to the medication list when evaluating sponsors' CY 2012 or CY 2013 PDE data for the 2014 or 2015 Plan Ratings, respectively. At that time, we will also evaluate the inclusion or exclusion of benzodiazepines and specified barbiturates in the measure calculation.

After considering the public comments received, we are finalizing the proposed language in § 423.100, with a grammatical clarifying modification. Pursuant to section 175(b) of MIPPA, this revision will be effective January 1, 2013.

3. Pharmacy Benefit Manager's Transparency Requirements (§§ 423.501 and 423.514)

We proposed implementing the provisions of section 1150A of the Act, as amended by section 6005 of the Affordable Care Act, with respect to Part D sponsors and the entities that manage prescription drug coverage under a contract with a Part D sponsor. We now codify the various reporting requirements from the proposed rule to promote transparency of financial transactions involving Part D sponsors and pharmacy benefits managers (PBMs) or other entities that provide pharmacy benefit management services at § 423.514, with a minor, technical correction to the language of § 423.514(e) regarding confidentiality of pharmacy benefits manager data. In addition, we are finalizing with modification the proposed definition of ''bona fide service fees'' in our regulations at § 423.501.

Comment: A commenter recommended that CMS define ''pharmacy benefits manager'' to encompass any entity or division of an entity, including a Part D sponsor itself, that performs any of the functions or activities for which reporting is required in order to clarify the scope of the regulation.

Response: We believe that we were clear in the proposed rule when we stated that this provision applies to both Part D sponsors and to entities that provide pharmacy benefits management services to Part D sponsors, for which we use the shorthand term of PBM. Further, section 1150A of the Act makes clear that a health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan is subject to all requirements and protections under this provision. Thus, we decline to introduce a definition of PBM in this regulation, but take this opportunity to emphasize that the entity's function is more important than the form of its name.

Comment: A number of commenters requested additional details regarding the proposed reporting requirements under paragraph (d)(3) of § 423.514. This provision would require reporting of the percentage of prescriptions for which a generic drug was available and dispensed by pharmacy type, which includes an independent, chain, supermarket, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public. Most commenters requested clarification on how to distinguish the various pharmacy types. A few commenters noted that neither plan sponsors, PBMs, nor pharmacy groups themselves differentiate among these pharmacy types. Several suggested ways for CMS either to provide crosswalks for PBMs and sponsors to help categorize the pharmacy types or to derive the data from available data sources.

Response: We agree that consistent definitions of independent, chain, supermarket, and mass merchandiser pharmacies are necessary for accurate reporting of this data element. We explored the ideas commenters submitted for CMS to provide crosswalks or to derive the data from existing data sources and determined that we could crosswalk National Provider Identifiers with a file from the National Council for Prescription Drug Programs to determine the data element in § 423.514(d)(2) (the percentage of all prescriptions that were provided through retail pharmacies as compared to mail order pharmacies). However, this approach cannot be used to categorize independent, chain, supermarket, and mass merchandiser pharmacies because they are not standard pharmacy classifications captured in industry databases or files. Thus, while we are finalizing § 423.514(d)(3) as proposed, we will issue further subregulatory guidance regarding this reporting requirement before requiring Part D sponsors to submit this information.

Comment: We received a number of comments regarding § 423.514(d)(4), under which we proposed to require reporting of the aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees) that a PBM negotiates that are attributable to patient utilization under the plan. In the proposed rule, we sought comment regarding whether there are differences between direct and indirect remuneration (DIR) under the Part D program and rebates, discounts, and price concessions ''attributable to patient utilization.'' Most commenters believed that there is no difference, with a couple of commenters mentioning that DIR under the Part D program is already based on price concessions for prescription drugs that are provided to Medicare Part D beneficiaries. Another commenter suggested that DIR under the

Part D program is broader than DIR attributable to patient utilization, and thus CMS should scale back the definition in the DIR reporting requirements.

Response: We agree that there is no substantive difference between the aggregate amount of rebates, discounts, and price concessions ''attributable to patient utilization'' and DIR under the Part D program. Per § 423.308 and our annual DIR reporting guidance, DIR is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Costs are incurred by the Part D sponsor when patients utilize Part D drugs, and thus we believe that ''rebates, discounts, and price concessions that are attributable to patient utilization'' are substantively the same as DIR under the Part D program. Further, rebates, discounts, and price concessions would not be negotiated unless Part D plan sponsors were purchasing prescription drugs from the manufacturer for use by their enrollees. Thus, we believe even rebates, discounts, and price concessions for things such as formulary placement for a particular product, administrative services, or generic dispensing incentives are indirectly attributable to patient utilization, such that they would be subject to the reporting requirements under § 423.514(d)(4).

Comment: One commenter requested that we clarify the authority under which we collect DIR and that Part D sponsors have no additional reporting requirements for DIR attributable to patient utilization.

Response: In the 2010 DIR reporting requirements, we collected PBM spread amounts aggregated to the plan benefit package level. We believe that with the addition of PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies to the existing DIR reporting requirements, Part D sponsors will meet the requirements to report the elements in § 423.514 (d)(4), (5), and (6). Beyond this change, no additional DIR reporting will be required to comply with section 1150A of the Act. We clarify that sections 1150A and 1860D–15(f)(1)(A) of the Act provide us with the authority to collect DIR data.

Comment: Several commenters recommended that instead of requiring the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate) by independent, chain, supermarket, and mass merchandiser pharmacy types, we allow the data to be reported by different and/or more general categories, such as mail order or retail pharmacy types.

Response: Consistent with 1150A(b)(1) of the Act, we believe that we must collect the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate) by independent, chain, supermarket, and mass merchandiser pharmacy types. Because reporting of this information is expressly required under the statute, we do not believe we have the authority to limit or change the scope of the reporting requirements. We note, however, that in implementing this requirement and all of the other reporting requirements under section 1150A of the Act, we have sought to minimize administrative burden where possible by relying on existing reporting mechanisms and avoiding duplicative reporting.

Comment: Some commenters favored greater transparency of prescription drug cost information than we proposed. Suggestions ranged from requesting that the proposed data elements under § 423.514(d) be reported with greater granularity to proposing additional reporting requirements beyond those proposed. Examples include requiring maximum allowable cost (MAC) lists for pharmacy reimbursement, requiring transparency regarding pharmacy network design, requiring reporting of a dispensing rate for when a lower cost drug could have appropriately been dispensed, requiring reporting of prompt payment rates, and requiring PBMs to report how patient data is used and disclosed.

Response: These suggestions are beyond the scope of the current rulemaking, which implements the specific reporting requirements of section 1150A. We note that some of the commenters' requests may be more appropriate as suggestions for revisions to prompt payment and pricing standard update requirements already codified at §§ 423.505(b)(21) and 423.520. Should we determine that the reporting of additional or more detailed information or disclosure of aggregated data is necessary and appropriate for the Part D program, we may consider some of the commenters' suggestions in the future.

Comment: Some commenters expressed concern about maintaining confidentiality of PBM-related data.

Response: We agree that maintaining the confidentiality of PBM-related data is important and are finalizing § 423.514(e) regarding the confidentiality of PBM data. The confidentiality protections under this provision are nearly identical to those in section 1150A, and specify that information disclosed by a Part D sponsor or PBM is confidential, and shall not be disclosed by the Secretary or by a plan receiving the information. The statute and the regulation recognize limited exceptions allowing the Secretary to disclose information disclosed by a Part D sponsor or PBM for certain limited purposes. These purposes are as the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII, to permit the Comptroller General to review the information provided, or to permit the Director of the Congressional Budget Office to review the information provided. (Section 1150A of the Act also permits disclosure of the information to States to carry out section 1311 of the Affordable Care Act. We have not incorporated this exception into § 423.514(e) because it is applicable to qualified health benefits plans offered through an exchange established by a State under section 1311 of the Affordable Care Act and is addressed in separate rulemaking.) Consistent with the statute, any disclosures pursuant to these exceptions, must be in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs.

Comment: A few commenters were concerned that the proposed definition of ''bona fide service fee'' in § 423.501 was too broad; for example, a commenter thought that the term ''patient care programs'' has no boundaries or limitations. Another suggested that we not qualify the definition of bona fide service fees with specific examples, while another would like us to provide not only examples of what is included in the definition of bona fide service fees but also examples of what is excluded from the definition.

Response: After considering these comments, we are modifying the proposed definition of bona fide service fees in § 423.501 by omitting the examples of bona fide services listed in the proposed definition. Bona fide services are subject to change as new ones are developed or other bona fide services are discontinued. Thus, we believe it is appropriate to elaborate on the definition of bona fide service fees in subregulatory guidance, as we have typically done in our DIR reporting guidance. We expect to provide such guidance to help Part D plan sponsors determine what is included in or excluded from the definition of bona fide service fees. We also note that by not including specific examples of such fees in the regulation, the definition of bona fide service fees in § 423.501 is consistent with the definition of bona fide service fees used in the Medicare Part B and Medicaid programs.

Comment: A few commenters questioned how CMS will monitor compliance with reporting requirements (for example, accurate reporting of bona fide service fees) and whether we intend to audit PBMs. A commenter asked for flexibility in CMS' policy on collecting PBM transparency data until sponsors have completed their next contract negotiations with PBMs.

Response: We intend to explore whether auditing PBMs will be necessary to ensure compliance with this provision. However, we do not believe it is necessary or appropriate to delay implementation of these reporting requirements because the statute, which was effective upon enactment, directs each PBM to provide to the Part D sponsor the data elements required by this rulemaking.

Comment: A commenter urged CMS to differentiate between PBM-owned mail order pharmacies and PBMs that contract for mail order pharmacy services because they believe that the Affordable Care Act should not be interpreted as requiring PBMs that own mail order pharmacies to disclose drug acquisition costs. Another commenter recommended that CMS clarify the reporting requirement with respect to PBM-owned mail order facilities in which there is no aggregate difference in the amount collected and the amount paid to the pharmacy. A commenter claimed that Medicare contracts between PBMs and sponsors must be 100 percent pass-through.

Response: If there is no difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays mail order pharmacies (that is, if Part D sponsors use pass-through pricing for their mail order pharmacies), then the amount should be reported under § 423.514(d)(6) as zero. Thus, for the purpose of collecting this data element, we do not believe that PBM-owned mail order pharmacies present unique challenges relative to PBMs that contract for mail order pharmacy services. Moreover, because only the aggregate amount of the difference between the amount the Part D sponsors pays the PBM and the amount the PBM pays retail pharmacies is reported, the PBM's drug acquisition costs drugs will not be disclosed.

Consistent with the discussion in our January 12, 2009 final rule, we also clarify that sponsors may use either the lock-in pricing or pass-through pricing approach when contracting with PBMs, but they must use the price ultimately received by the pharmacy (or other dispensing provider) as the basis for calculating beneficiary cost sharing, total drug spend, and cost reporting to CMS. (See § 423.100 for the definition of negotiated price and 74 FR 1505 through 1511 for more details.)

Comment: A commenter requested that CMS clarify whether the total number of prescriptions dispensed reported under § 423.514(d)(1) is based on PDEs or actual claims. If it is based on PDEs, the commenter believed CMS should clarify that it would still be the Part D sponsor's responsibility to hire a data validation auditor to evaluate the validity of the reports, as opposed to passing this responsibility to the PBM.

Response: We do not plan to institute a new requirement on plan sponsors or PBMs to collect this data element as they already report it on PDEs. We remind plan sponsors that they must maintain audit trails to PDE source data. We expect that the plan will be able to directly link any PDE to the individual claim transactions from which the PDE was extracted, and will conduct audits of PDE data to ensure the accuracy of payment. Part D sponsors have the discretion to negotiate terms with each PBM that obligate the PBM to participate in maintaining audit trails. Also, consistent with § 423.505(k), each year Part D sponsors must certify that their PDEs and DIR reports, among other data, are accurate, complete, and truthful. While Part D sponsors remain accountable for their certifications, they have the discretion to negotiate with their first tier and downstream entities concerning the entities' participation in the data validation activities that must support each certification.

Comment: A commenter suggested that CMS should provide an annual report on the best and worst plans with respect to the reporting requirements in paragraph (d).

Response: We believe that this comment is out of scope as section 1150A of the Act addresses PBM reporting requirements, confidentiality of PBM-related data, and penalties for failure to provide pharmacy benefits manager data.

After considering the comments received, we are finalizing the policy as proposed with one modification to the definition of ''bona fide service fees'' in § 423.501. We have also made a minor, technical correction to the language of § 423.514(e).

B. Strengthening Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. In our opinion, it is appropriate to provide for reinstatement of beneficiaries in the section 1876 cost plans from which they were disenrolled for failing to pay premiums when they can establish good cause for their failure to pay. We anticipate that finalizing this provision will result in uninterrupted plan coverage for eligible beneficiaries and thereby improve access to healthcare for individuals such as those with chronic conditions requiring continual monitoring and medication. Similarly, we expect that requiring sponsors to provide enrollees in MA plans with uniform ID cards which all providers will be able to easily recognize will facilitate access to health care for those beneficiaries. We also believe that calculating creditable coverage by excluding the value of additional coverage in the coverage gap and the manufacturers discount—the standard that qualifies retiree drug coverage for the retiree drug subsidy—will mean a beneficiary receiving retiree drug coverage will be less likely to be assessed a late enrollment penalty if he or she subsequently decides to enroll in a Part D plan. Enabling health care professionals to request Independent Review Entity (IRE) reconsiderations of Part D coverage determinations on behalf of enrollees without having to obtain signed appointment of representative forms will, in our opinion, lessen the burden faced by providers seeking to assist enrollees with appeals and will encourage more health care professionals to help beneficiaries access this level of the appeals process. The foregoing proposals and the changes considered are set forth in Table 3.

TABLE 3—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Preamble section	Provision	Part 417		Part 422		Part 423		Part 483	
		Subpart	Subpart	Section	Section	Subpart	Section	Subpart	Section
II.B.1	Good Cause and Reinstatement into a Cost Plan.	Subpart K	417.460	N/A	N/A	N/A	N/A	N/A	N/A
II.B.2	Requiring MA Plans to Issue Member ID cards.	N/A	N/A	Subpart A	422.111	N/A	N/A	N/A	N/A
II.B.3	Determination of Actuarially Equivalent Creditable Prescription Drug Coverage.	N/A	N/A	Subpart K	422.56	N/A	N/A	N/A	N/A
II.B.4	Who May File Part D Appeals with the Independent Review Entity.	N/A	N/A	N/A	N/A	Subpart M	423.600 423.602	N/A	N/A

1. Good Cause and Reinstatement Into a Cost Plan (§ 417.460)

Current regulations at § 417.460(c) specify that an HMO or competitive medical plan may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount (for example, the plan attempted to contact the member by phone or mail) and sent the enrollee written notice of the proposed disenrollment (including an explanation of the enrollee's right to a hearing under the HMO's or competitive medical plan's grievance procedures). Cost plans also have the option of not disenrolling members who fail to pay their premiums or cost-sharing. A plan may adopt either policy and must apply it consistently to all members in the plan.

Individuals who are disenrolled from an MA or Part D plan for failure to pay premiums are generally ineligible to regain MA or Part D coverage until the next Annual Election Period. However, in some of these cases, there may be extenuating circumstances that would make reinstatement appropriate. Thus, in the April 2011 final rule (76 FR 21511), we established provisions at §§ 422.74 and 423.44 that allow individuals, who are disenrolled from MA and Part D plans for failure to pay premiums, to request reinstatement into their former plan based on good cause and the ability to pay all arrearages. These MA and Part D rules provide alignment with the existing Part B policy regarding delinquent Medicare Part B premium payments.

In the October 11, 2011 proposed rule (76 FR 63036), we proposed to extend the right to request reinstatement for good cause to beneficiaries enrolled in cost plans. Specifically, we proposed to amend § 417.460(c) to allow reinstatement of enrollment for good cause following involuntary disenrollment, based on failure to pay premiums or other cost-sharing amounts, to a cost plan. Section 417.460(c) provides that—

- To be eligible for reinstatement, the enrollee would have to pay all outstanding arrearages, including premiums that accrued during the period of disenrollment;
- The standard for good cause would be similar to the standard established under MA and Part D (for example, unexpected, prolonged hospitalization or loss of home or severe impact by fire); and
- An individual who is involuntarily disenrolled within the same timeframe from both his or her cost plan and a standalone PDP (not affiliated with the cost plan), would have to seek separate good cause determinations for reinstatement into each plan.

Comment: CMS received several comments on this proposal, all of which expressed broad support and concurrence with our intent to mirror the existing MA and Part D requirements. A commenter expressed regret with our determination that good cause would not exist if the sole basis for requesting reinstatement is a change in an individual's financial circumstances. The commenter suggested that such an individual might eventually find the means to afford the plan's premiums, in which case, she or he should not be prohibited from reinstatement and the opportunity to reestablish relationships with previous providers. In addition, the commenter believes that beneficiaries should be able to appeal a denial of reinstatement.

Response: The intent behind this provision was to give cost plan enrollees the same protections that we currently extend to MA and Part D plan enrollees. As such, we do not believe that it would be appropriate to expand these protections to include either additional factors that meet the good cause standard or appeal rights when a request for reinstatement is denied. It is important to note that denying a beneficiary's request for reinstatement does not result in the loss of Medicare coverage. Instead, individuals who are involuntarily disenrolled from a cost plan revert back to Original Medicare and are free to maintain their relationships with established providers. In addition, if an individual's financial circumstances improve over time, she he can re-enroll during the cost plan's next period of open enrollment.

We appreciate the comments that were submitted on this provision and will be finalizing this proposal without modification.

2. Requiring MA Plans to Issue ID Cards (§ 422.111)

Pursuant to section 1860D–4(a)(1) of the Act and § 423.120(c), and consistent with, common industry practice as described in the Medicare Marketing Guidelines (*http://www.cms.gov/ManagedCareMarketing/03_FinalPartCMarketingGuidelines.asp*), Part D sponsors must issue and re-issue as appropriate a card or other technology that enrollees can use to access negotiated prices for Part D covered drugs. While we have made recommendations with respect to member identification (ID) cards for Medicare Advantage (MA) Preferred Provider Organization and Private Fee-for-Service products through our Medicare Marketing Guidelines (*http://www.cms.gov/ManagedCareMarketing/*), we have issued no related regulatory requirements. Many MA organizations issue ID cards to their enrollees, but, absent such a requirement in regulation, we cannot ensure that all MA organizations issue cards to their members or that the cards contain certain information at a minimum and other information necessary for consistency of information across such documents. Thus, we believe it is important to establish requirements for the MA member ID cards to ensure that key information (such as the plan's customer service number and the member ID number) is on the card so that enrollees can access care. Specifically, we proposed to require that ID cards contain the following information: (1) For an MA PPO or PPFS plan, a statement that Medicare Limiting Charges apply; (2) an address for the plan's Web site; (3) a customer service number; and (4) the individual identification number for each enrollee, to clearly identify that he or she is a member of the plan.

We indicated that implementation of these provisions would ensure providers have easy access to the necessary information for verifying coverage and processing claims. Therefore, under our authority at section 1852(c) of the Act (to require that MA organizations disclose MA plan information upon request), at section 1856(b)(1) of the Act (to establish standards by regulation) and section 1857(e) of the Act (to specify additional contractual terms and conditions the Secretary may find necessary and appropriate), we proposed to amend § 422.111 by adding a new paragraph (i) to expressly require that MA plans issue and re-issue, as necessary, a card that contains certain information and enables enrollees to access all covered services.

Comment: Several commenters expressed support for the proposal to require MA plans to issue ID cards. Additionally, they offered suggestions for specific ID card requirements: (1) add an identifier to the card for individuals who receive Medicaid or are QMBs; and (2) adopt the Workgroup on Electronic Data Interchange (WEDI) standards for medical ID cards. In addition, one commenter said that we should exclude the Medicare Limiting Charges statement because of card crowding.

Response: We appreciate the thoughtful comments. In light of the recommendations that we add more information to the ID card, and realizing that there is limited space in which to include such information, we will be issuing further guidance in this area based on accepted industry practice. In developing such guidance, we will also consider the commenter's concern about the possible lack of space on the card if we were to include our proposed statement regarding Medicare Limiting Charges.

Comment: A commenter questioned whether this requirement applies to section 1876 cost plans.

Response: Yes. With the final publication of these regulations, § 417.427 will be amended to require section 1876 cost plans to follow the disclosure requirements contained in § 422.111. As the ID provision is part of these disclosure requirements, as of the publication of these regulations, section 1876 cost plans will be required to issue ID cards.

After consideration of the public comments received, we are finalizing the policy with the following modification: We are removing the specific information requirements from the ID card provision (§ 422.111(i)).

3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

Section 1860D–22 of the Act outlines the special rules for employer-sponsored programs. Subsection 1860D–22(a) of the Act establishes that the Secretary shall provide payment to sponsors of qualified retiree prescription drug plans that provide equivalent or better coverage than the actuarial value of standard prescription drug coverage. The Affordable Care Act amended section 1860D–22(a)(2)(A) of the Act by adding a provision that changed the formula for determining the actuarial equivalence of retiree prescription drug coverage to the defined standard coverage. Consistent with this provision, qualified retiree prescription plans, in their attestation of actuarial equivalence, must disregard the value of any discount or coverage provided during the coverage gap provided under standard prescription drug coverage. Thus, in the April 2011 final rule (76 FR 21478), we amended § 423.884(d) to remove the value of any discount or coverage provided during the coverage gap from the valuation of standard prescription drug coverage when comparing the value of the retiree drug subsidy (RDS) calculation to determine valuation of the RDS coverage.

Section 1860D–13(b)(4) of the Act defines creditable prescription drug coverage to include coverage that at least meets the actuarial equivalence requirements in 1860D–13(b)(5)(A) of the Act. This provision requires the cost of prescription drug coverage to have an actuarial value that equals or exceeds the actuarial value of the standard Medicare prescription drug benefit (as determined under section 1860D–11(c) of the Act). The Affordable Care Act established two standard Medicare prescription drug benefits. Thus, there are now two calculated actuarial values for the standard prescription drug benefit—one value that would apply for standard prescription drug coverage when establishing the low-income subsidy and another value that would apply to applicable beneficiaries. As a result, we needed to clarify which actuarial equivalence standard is used for the valuation of creditable prescription drug coverage. Retiree prescription drug coverage is the most common source of creditable coverage, therefore we proposed to align the actuarial value calculation we use for purposes of section 1860D–13(b) of the Act with the actuarial value calculation used to determine the value of the retiree drug subsidy. By using the same values for both determinations, we ensure that RDS individuals, who are enrolled in plans that meet the actuarial equivalence value of defined standard prescription drug coverage as provided under § 423.884(5)(iii)(C), are not subject to the LEP under § 423.46 if they subsequently enroll in a Part D plan.

To this end, we proposed to amend § 423.56(a) to exclude the value of gap discounts or coverage, so that the definition of creditable coverage is consistent with the calculation of the actuarial value of RDS coverage in § 423.884(d). We also proposed to revise the reference to ''CMS actuarial guidelines'' in § 423.56(a) to read ''CMS guidelines,'' to provide additional flexibility in issuing interpretive guidance on the definition of creditable coverage.

Comment: All commenters who addressed this issue were in favor of the proposal. Commenters indicated that CMS' changes would ensure that more employer-sponsored plans will be determined creditable, so enrollees will not be subject to the Part D late enrollment penalty if they choose to switch from employer-sponsored coverage to Part D coverage.

Response: We appreciate the commenters' support of the proposal and agree with their position that this approach will enable beneficiaries who switch from employer-sponsored creditable prescription drug coverage to a Part D plan to do so without incurring a late enrollment penalty.

Comment: A commenter indicated support to exclude the late enrollment penalty (LEP) from the calculation of creditable coverage and requested that CMS provide employer-sponsored plans with the LEP amounts to effectuate the proper calculation.

Response: The calculation for creditable coverage for qualified retiree prescription drug plans does not include the LEP. Further, because the LEP is not part of the formula to determine and attest creditable coverage, we do not believe it is necessary to share the LEP amounts with employer-sponsored plans.

We appreciate the comments that were submitted on this provision and will be finalizing this proposal without modification.

4. Who May File Part D Appeals With the Independent Review Entity (§§ 423.600 and 423.602)

Section 1860D–4(h) of the Act directs the Secretary to establish a Part D appeals process that is similar to the appeals process used for MA appeals. The Parts C and D appeals procedures are set forth in Subpart M of Parts 422 and 423 of our regulations, respectively. In our January 12, 2009 final rule (74 FR 1494), we amended both sets of regulations to strengthen enrollee access to the Part C and Part D appeals processes. Specifically, we amended the MA appeals regulations at § 422.582 to permit physicians to request standard plan reconsiderations of pre-service requests on behalf of MA enrollees. Consistent with section 1860D–4(g) of the Act, we made a corresponding change to the Part D regulations at § 423.580, allowing prescribing physicians and other prescribers to request standard redeterminations on behalf of enrollees. Allowing prescribers to request coverage determinations and plan level appeals on behalf of enrollees has significantly enhanced enrollee access to these processes.

Subsequent program experience has taught us that these changes to the Part D appeal process may not go far enough in terms of improving access to the Part D appeals process, as explained later in this section. Consequently, we proposed to revise the Part D regulations at § 423.600 to allow prescribing physicians and other prescribers to request Independent Review Entity (IRE) reconsiderations on behalf of enrollees. We also proposed making a corresponding change to the notice provisions at § 423.602(a).

Currently, the Part D IRE reports that approximately 46 percent of the cases it dismisses lack a valid appointment of representative (AOR) form, and that the overwhelming majority of these dismissed appeals (close to 90 percent) are initiated by prescribers. Such dismissals impede prescribers from assisting enrollees in obtaining timely independent review of their cases which creates the potential for delays in prescription drug access. Furthermore, given a prescriber's ability to act on behalf of an enrollee in requesting Part D plan level appeals, prescribers frequently express dissatisfaction with not being able to also assist patients with IRE level appeals and the perceived burden associated with becoming the enrollee's appointed representative. Clearly, this rule will significantly reduce the number of requests for review that the Part D IRE dismisses due to the lack of an AOR form. In addition, because the IRE will no longer have to seek an AOR form, it will be able to immediately initiate substantive review of these cases. Thus, we believe this change will enhance beneficiary access to the appeals process and better ensure prompt IRE decisions on whether requested drugs are covered under Part D.

Under this final rule with comment period, the regulations will continue to require a Part D enrollee, or a prescriber acting on his/her behalf, to request IRE review; adverse redeterminations will not be automatically forwarded to the IRE. We considered requiring auto-forwarding of adverse redetermination requests under the Part D program, but we continue to believe that in order to obtain IRE review, the statute requires the enrollee (or someone acting on the enrollee's behalf) to request such review. (See the January 28, 2005 final rule (70 FR 4193) for a discussion of this issue.) Although section 1860D–4(h) of the Act states that only the Part D eligible individual shall be entitled to bring an appeal to the IRE, we do not interpret this language as precluding a prescriber from acting on a Part D enrollee's behalf in requesting IRE review. As required by section 1860D–4(h) of the Act, this change makes the MA and prescription drug benefit programs' appeals processes more similar, by giving Part D prescribers a mechanism to assist enrollees in accessing IRE review. In the MA program, the regulatory requirement that adverse plan reconsiderations be auto-forwarded to the IRE essentially gives physicians acting on behalf of enrollees direct access to the IRE reconsideration process. Also, as explained in our January 2009 final rule, allowing prescribers to request IRE appeals on behalf of enrollees does not present a conflict of interest because Part D prescribers are generally not entitled to payment from the enrollee, pharmacy, or plan for the prescribed drug, and therefore, do not have a financial interest in the outcome of appeals in the same manner as physicians requesting appeals under the MA program. Furthermore, we believe that an enrollee's prescriber has already been selected by the enrollee and occupies a position of trust. A prescriber is in a good position to know whether an independent review is warranted and is in the best interest of his or her patient.

This change should reduce administrative burdens under the IRE appeal process by eliminating the need for prescribers to routinely obtain AOR forms from enrollees and permitting prescribers to assist their patients in the appeals process without taking on the added responsibilities attendant to being an appointed representative. In contrast to the ongoing authority of appointed representatives, this change will allow a prescriber to act on an enrollee's behalf on an as-needed, case-by-case basis. A completed AOR form is not necessary or advisable for prescribers who are only seeking to assist Part D enrollees in exercising their own appeal rights under the statute. Prescribers will not have the same authority as an appointed representative, including the right to bring appeals at any level. Instead, we envision that from the time of the initial IRE appeal request, the prescriber's role will remain what it has been, providing a supporting statement or the clinical information necessary to approve coverage, if appropriate. Accordingly, we believe that this change will promote enrollee access to the Part D appeals process, reduce the burden on the prescriber community, and allow a more efficient use of appeals resources.

We are also making a corresponding change to § 423.602(a) to specify that the IRE is responsible for notifying the prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The enrollee will also receive a written decision notice from the IRE, thereby ensuring that enrollees are fully informed about the review process and able to participate if they choose to do so.

As in §§ 422.582 and 423.580, prescribers must notify enrollees whenever they request IRE review on their behalf. We intend to issue additional operational guidance with respect to how this requirement may be satisfied. Finally, we make clear that this final rule with comment period addresses only the right of a prescriber to file an appeal on behalf of an enrollee at the IRE level. Other individuals who wish to act on behalf of an enrollee in filing an appeal must continue to do so as the enrollee's representative.

Comment: Most commenters expressed support for the proposal, noting that allowing prescribers to file IRE appeal requests on behalf of enrollees without becoming that enrollee's appointed representative would reduce administrative burdens on prescribers, limit dismissals of reconsideration requests, make the appeals processes under Parts C and D more similar, and enhance beneficiary access to the Part D appeals process.

Response: We appreciate the commenters' support and are finalizing the proposed revisions without modification.

Comment: A few commenters expressed concerns that the proposed change may negatively affect plan sponsors' quality ratings because it will likely result in an increase in the number of IRE appeal requests and potentially result in a higher IRE overturn rate.

Response: We agree that this change is likely to increase the number of IRE reconsideration requests, as discussed in the regulatory impact analysis for this provision. To the extent that a plan sponsor's IRE reversal rate increases as a result of this change, plan sponsors may wish to review their internal policies and procedures to ensure compliance with CMS subregulatory guidance instructing them to conduct reasonable and diligent outreach efforts to prescribers and enrollees when supporting statements or clinical information necessary to make a coverage decision are absent or incomplete.

Comment: A few commenters believe that allowing prescribers to file IRE appeals may violate section 1860D–4(h) of the Act, which specifically states that only the enrollee can bring an appeal to the IRE. The commenters note that the statutory language differs from the language related to Part C IRE appeals, and further suggest that Congressional intent was to limit the Part D IRE appeals process to individuals acting on behalf of enrollees, disallowing individuals other than the enrollee from initiating IRE appeals absent an AOR form.

Response: We disagree with the commenters. This provision does not give prescribers appeal rights; it merely allows them to file an appeal with the IRE on behalf of an enrollee. We believe that an enrollee's prescribing physician or other prescriber is in the best position to provide the necessary medical rationale and documentation to support a favorable coverage decision. As we stated in the proposed rule, the revised regulation will require prescribers to notify enrollees that the request is being made. We intend to issue additional operational guidance with respect to how this requirement may be satisfied in a manner similar to the notification requirements for prescriber-initiated redeterminations.

Comment: A few commenters recommended that CMS limit IRE review to include only the information provided by the prescriber at the coverage determination and redetermination levels. These commenters believe that prescribers often delay providing full clinical information until an appeal reaches the IRE level and the IRE solicits it. Commenters note that if plans received the same information they may reach the same conclusion as the IRE in less time and at a lower cost.

Response: We strongly disagree with the commenters. The proposed rule was not intended to modify the IRE review process itself in any way; it only proposed to modify who may initiate an IRE appeal. We are retaining existing regulatory and subregulatory guidance regarding the requirement that the IRE solicit the views of the prescriber and retain a written account of those views in the IRE's record.

Additionally, we have not seen any indication that prescribers are intentionally withholding applicable clinical information in either the Part D coverage determination or appeals processes. As we noted in the proposed rule, prescribers do not have independent standing in Part D appeals, and generally are not entitled to payment from the enrollee, pharmacy, or plan for the drug being requested and therefore do not have a financial interest in the outcome of Part D appeals. In these cases, the prescriber is merely trying to assist the enrollee in obtaining coverage for a drug the prescriber believes is medically necessary. Prescribers have no incentive to withhold information that would support coverage. To the extent that the IRE routinely solicits and obtains information from a prescriber that was not provided during the initial coverage determination or redetermination, plan sponsors may wish to review their internal policies and procedures to ensure compliance with our subregulatory guidance, which instructs plan sponsors to conduct reasonable and diligent outreach efforts to prescribers and enrollees when necessary supporting statements or clinical information are absent or incomplete.

Comment: CMS received several comments related to enrollee notification of a prescriber-initiated IRE appeal requests. Some commenters recommended that CMS issue guidance requiring prescribers to notify enrollees when they file an appeal on the enrollee's behalf. One commenter expressed a belief that, under the proposed change, plan sponsors would need to exercise additional oversight such as contacting enrollees to ensure that prescribers are appropriately notifying enrollees and review any form or document the prescriber uses to make the IRE appeal request. Another commenter recommended that CMS not require plan sponsors or the IRE to obtain proof from the prescriber that the enrollee was notified of the requested IRE review made on their behalf. Finally, one commenter stated that a prescriber must obtain the enrollee's consent in order to file an appeal with the IRE.

Response: We do not require and do not expect plan sponsors to conduct any type of review or oversight to determine whether prescribers have notified enrollees that they are initiating an IRE appeal on their behalf. We intend to issue guidance to the IRE with respect to making a reasonable determination of whether the enrollee has notice of the prescriber's request for a reconsideration on the enrollee's behalf. This provision merely eliminates the requirement that a prescriber obtain an enrollee's express consent (through a properly executed AOR form) in order to initiate an IRE appeal on behalf of the enrollee.

Comment: A commenter requested that plan sponsors be informed of all IRE submissions and determinations so that they can evaluate their internal processes and provide oversight of delegated entities.

Response: We agree with the commenter. In accordance with current processing requirements, the IRE will continue to request the plan sponsors' case files subsequent to all valid requests for IRE reconsideration. The proposed change to § 423.602(a) does not change the requirement that the IRE notify all parties, including the plan sponsor, of the reconsideration decision. Thus, processes for communication with and notification to plan sponsors with respect to prescriber-initiated reconsiderations will be identical to the current processes for enrollee-initiated reconsiderations.

Comment: Several commenters recommended that CMS require auto-forwarding of all adverse redeterminations to the Part D IRE, as is currently done with adverse plan reconsiderations in the MA program.

Response: While we understand that auto-forwarding all adverse redeterminations to the IRE would enhance enrollee access to the Part D appeals process, we believe that this practice would be inconsistent with the statute. As we stated in the proposed rule, we interpret the statutory language related to Part D appeals to require the enrollee (or someone acting on his or her behalf) to affirmatively request IRE review.

Comment: A commenter recommended that CMS include information on who may file appeals with the IRE on the Medicare Web site, in Medicare & You and in plan communications to increase awareness of appeal options.

Response: We agree with the commenter and will ensure that all relevant CMS materials are updated to reflect this change after the final rule has been published. Part D plan sponsors are also required to maintain current information regarding the Part D appeals process on their plan Web sites and in annual enrollment materials.

Comment: A commenter requested that notification of IRE decisions for appeals initiated by prescribers be provided to the enrollee either by the provider or the IRE.

Response: We agree with the commenter that enrollees must receive written notification of IRE appeal decisions. As stated previously, we are finalizing the proposed corresponding change to § 423.602(a), which specifies that in all cases the IRE is responsible for notifying the enrollee (as well as the prescriber) of its decision, including when a prescriber makes a request on behalf of the enrollee.

Comment: A commenter sought clarification on whether a prescriber still needs to be appointed by the enrollee to file a request for IRE reconsideration.

Response: The purpose of the proposed change is to eliminate the need for a prescriber to obtain representative status in order to initiate an IRE appeal on the enrollee's behalf. Therefore, we are finalizing the proposed regulation text to state that, upon providing notice to the enrollee, the prescribing physician or other prescriber may request an IRE reconsideration on behalf of the enrollee. An ''appointment'' is no longer required.

Comment: A commenter noted that a prescription may be denied by a Part D plan at the point of sale for a variety of reasons, and that a coverage determination should be required before proceeding to the IRE as a majority of appeals could be resolved through plan adjudication.

Response: We agree with the commenter. The proposed change allowing prescribers to file IRE appeals on behalf of an enrollee does not eliminate the requirement to exhaust plan level reviews before requesting IRE review. Under the proposed change, enrollees, their representatives and physicians or other prescribers may make a request for IRE review only after the Part D plan sponsor has made an adverse redetermination decision.

Comment: A commenter requested clarification that ''prescriber'' refers only to the physician, PA or NP who wrote the order for the drug in dispute.

Response: Under our proposed change to § 423.600, the ''prescribing physician or other prescriber''—the individual who wrote the order for the drug in dispute—will be the only person authorized to make an IRE appeal request on behalf of an enrollee (absent an authorized or appointed representative).

Comment: A commenter recommended that IRE appeal requests be limited to prescribing physicians and not to a physician designee.

Response: We agree that the proposed change only allows prescribing physicians and other prescribers to initiate IRE appeals on behalf of enrollees. However, we understand that medical and administrative staffs perform various functions for physicians (such as calling in prescriptions or responding to requests for medical records) these same staff should be allowed to assist prescribers in submitting Part D IRE appeal requests and providing any necessary clinical documentation. We will develop additional subregulatory guidance around this process.

Comment: A commenter stated that allowing prescribers to initiate IRE appeals on behalf of enrollees will contribute to the increasing problem of overutilization of medications caused by prescribers who continue to prescribe drugs that are not medically necessary.

Response: We understand the commenters concerns, but disagree with the suggestion that the proposed provision will lead to overutilization. We are only allowing prescribers to request coverage at the IRE level. The decision whether to overturn the adverse redetermination will continue to be made by the IRE based on statutory and regulatory guidelines and applicable clinical documentation.

Comment: A commenter encouraged CMS to ensure that prescriber requests for IRE reconsideration are consistent throughout the Part D and MA programs.

Response: We are seeking to make the Part D and MA programs more similar through this regulatory change. However, as noted previously, we believe the statutory differences with respect to IRE reconsiderations do not allow for these processes to be identical.

Comment: CMS received a number of comments related to fees charged by prescribers who assist enrollees with Part D appeals. Several commenters urged CMS to reexamine the policy surrounding ''allowable extra fees,'' stating that Part D and MA program appeals are rarely successful without physician support and allowing physicians to charge fees for providing letters of medical necessity or producing medical records creates an unnecessary tension in the doctor-patient relationship. Some commenters requested that CMS prohibit physicians or other prescribers who file IRE appeals on behalf of enrollees, from charging enrollees any fee for assistance unless an enrollee has agreed to the fee in writing. Other commenters requested that CMS issue guidance related to reasonable fees. A number of commenters also noted that CMS rules related to appointment of representatives include a provision that a physician representative may waive a fee for representing a beneficiary.

Response: Subpart M does not address fees charged by physicians or other prescribers; therefore, we believe these comments are outside the scope of the proposed regulation.

As stated previously, we are finalizing the proposed changes without modification. However, we are, changing the effective date of this provision from 60 days after the publication of this rule to January 1, 2013, to clarify that prescribers may not begin requesting reconsiderations on behalf of the beneficiary until the 2013 plan year.

5. Independence of LTC Consultant Pharmacists (§ 483.60)

In our October 11, 2011 proposed rule (76 FR 63038), we noted that under sections 1819(b)(4) and 1919(b)(4) of the Act, long term care (LTC) facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the needs of each resident. This requirement is codified in regulations at § 483.60, which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility, including a drug regimen review at least once a month for each facility resident. We explained that, as a result of their role in LTC facilities, LTC consultant pharmacists may exercise significant influence over the drugs that LTC facility residents receive.

We noted that nursing homes commonly contract with a single LTC pharmacy for prescription drugs for facility residents. Very often the same LTC pharmacy then also contracts with the facility to provide consultant pharmacists for required consultation on all aspects of the provision of pharmacy services in the facility, including the monthly resident drug regimen reviews. We indicated that, in verbal conversations with industry representatives, we had been informed that some LTC pharmacies provide the consultant pharmacists to nursing homes at rates that may be below the LTC pharmacy's cost and below fair market value.

We expressed our concern with the potential effect on patient safety and quality of care for nursing home residents regarding the various contractual arrangements involving LTC facilities, LTC pharmacies, pharmaceutical manufacturers and/or distributors, and the LTC consultant pharmacists that may be provided through LTC pharmacies directly or indirectly to LTC facilities. We noted these arrangements may take many forms and mentioned the practice of LTC pharmacies' providing consultant pharmacists to nursing homes at below cost or fair market value as one such type of arrangement. We noted also that any such arrangements have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations. We indicated our concern that the lack of independence of the consultant pharmacist from the interests of the LTC pharmacy or other LTC pharmacy-related organization may lead to recommendations that steer nursing homes to recommend or use certain drugs for their residents. We noted this could result in the overprescribing of medications, the prescribing of drugs that may be inappropriate for LTC or geriatric residents, or the use of unnecessary or inappropriate therapeutic substitutions. We remarked that such potential outcomes could pose serious health-related consequences to some nursing home residents' health and safety.

In our October 11, 2011 proposed rule (76 FR 63039), we referenced the claims brought by qui tam relators under the False Claims Act and cited research findings, HHS Office of Inspector General review findings, and nursing home survey and certification data to demonstrate that our concerns were not merely theoretical. We acknowledged that our findings did not directly connect LTC pharmacy relationships with consultant pharmacists to the research findings and survey results; however, we believed it was reasonable to presume that the incentives present in the relationships among some consultant pharmacists, LTC pharmacies, and drug manufacturers could influence the prescribing practices reflected in the data. As a result, we expressed our belief that requiring the independence of consultant pharmacists was necessary and appropriate and were considering making such a change. We solicited comments on our understanding in this matter.

In our October 11, 2011 proposed rule (76 FR 63040), we stated that we believed severing the relationship between the consultant pharmacist and the LTC pharmacy, pharmaceutical manufacturers and distributors, and any affiliated entities would further protect the safety of LTC residents because it would ensure that financial arrangements would not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents. Therefore, we indicated that we were considering requiring that LTC consultant pharmacists be independent of any affiliations with the LTC facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities and believed such a requirement would be necessary to ensure that consultant pharmacist decisions were objective, unbiased, and in the best interest of nursing home residents. LTC facilities would use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based on the best interests of the resident. We expressed our belief that this could be achieved only if the consultant pharmacist were working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents.

We noted the changes we were considering would use the authority available under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to require that LTC consultant pharmacists be independent. The cited statutory provision gives the Secretary authority to establish ''such other requirements relating to the health, safety, and well-being of residents * * *.'' We stated we were considering requiring that LTC facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also noted we were considering including a definition of the term ''independence'' to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

Finally, we noted our understanding that some LTC consultant pharmacists may perform approximately 60 drug regimen reviews in a day. We indicated we suspect that this rate may be too high, given our expectation that independent consultant pharmacists would conduct more thorough drug regimen reviews, monitoring for drug side effects and efficacy. Therefore, although we did not propose to codify changes to the drug regimen review requirements, we solicited public comment on best practices related to the conduct of drug regimen reviews and stated we would use these comments to inform possible future rulemaking regarding the drug regimen review requirements.

Comment: CMS received many responses to our request for comment on our understanding of the problems associated with conflict of interest involving LTC consultant pharmacists. A significant number of commenters who identified themselves as current or former consultant pharmacists either acknowledged they had experienced conflict of interest in the past or confirmed our understanding that conflict of interest were an on-going problem. Several of these commenters claimed that conflicts of interest have been widespread and alleged that patient care suffers because of it. A number of these commenters wrote anonymously stating they feared retribution from their pharmacy employers. A commenter asserted that the rules LTC pharmacies placed on their employee consultant pharmacists strongly influenced utilization. This, they note, often resulted in a higher number of medications per resident and use of inappropriate drugs. Commenters who had witnessed or experienced conflict of interest described practices associated with it that included the following:

• Several commenters indicated their LTC pharmacy gave consultant pharmacists a list of ''preferred'' drugs; that is, drugs for which the LTC pharmacy receives preferred pricing or higher rebates from the pharmaceutical manufacturer, to be used for making their medication recommendations.

• A few commenters described their LTC pharmacy's therapeutic interchange program, which involves the consultant pharmacist recommending a change from a prescribed non-preferred drug to one of the pharmacy's preferred drugs. A commenter characterized therapeutic interchange to rebated drugs as ''big business'' for the pharmacy. Another commenter explained that, once a change recommendation was made by the consultant pharmacist, the LTC pharmacy automatically generated a fax notice to the prescriber requesting the he or she sign the notice to approve the therapeutic interchange. An additional commenter indicated that the consultant pharmacists' medication change recommendations were communicated in the form of letters to the prescriber prepared by the corporate clinical department of the pharmacy.

• Several commenters explained that consultant pharmacists' performance evaluations and bonuses were based on the market share of particular brand name drugs in the LTC facility. Thus, as the commenters noted, consultant pharmacists had financial incentives to make medication recommendations that enabled the facility market-share targets to be met.

• Many commenters stated that they had first-hand knowledge that LTC pharmacies continue to charge below-market rates for the LTC consultant services as a means of acquiring the LTC facility's pharmacy business, noting that this remains a common practice. Some of these commenters charged that the pharmacies recovered their costs for the consultant pharmacist services by requiring the consultant pharmacists to recommend drugs that generated the highest profit for the pharmacy.

• Many commenters charged that the consultant pharmacists' drug regimen review quotas were so high that sufficient time was not available to perform a thorough review of the residents' medication regimens and make good recommendations. One commenter cited a minimum drug regimen review quota of 1,500 reviews per month. Another commenter reported that, when a large LTC pharmacy organization acquired the pharmacy at which the commenter had been employed, the new management required that the commenter perform the same number of drug regimen reviews as the commenter had been performing previously, but also that the commenter spend 2 days per week dispensing. As a result, the time available for the commenter to perform the same number of medication reviews was decreased by 40 percent.

• Some commenters asserted that by limiting the time available to conduct them, the drug regimen reviews were perfunctory. Others described how the drug regimen review requirements were subverted. For example, a commenter contended that the consultant pharmacists employed by an LTC pharmacy were performing the medication reviews at the pharmacy rather than the facility and, thus, had no access to medication administration records, physician and nursing assessment notes, lab results, or other information available in the residents' medical records. Another asserted that an LTC pharmacy organization had its consultant pharmacists review the residents' medication administration records, not the entire medical record, thus missing lab values and other assessments and notes.

• Many commenters agreed that consultant pharmacists should be free from conflict of interest and their medication recommendations should be based solely on the residents' best interests. Finally, however, many other commenters stated that they never experienced any pressure in the conduct of their consultant pharmacist activities, nor had they seen others pressured, and thus they believed that conflict of interest is not an issue for consultant pharmacists.

Response: We appreciate the confirmation of our understanding that conflict of interest may be a problem for many LTC consultant pharmacists. We recognize that a significant number of commenters disagreed with our understanding and, thus, the problem may not be universal. We believe the comments suggest that the problem has been addressed in some places and not in others, is more widespread in some places and therefore more evident, or is associated with a particular LTC pharmacy or pharmacies, particular LTC facilities or chains or pharmaceutical manufacturers or manufacturer representatives.

However, the reports of conflict of interest are sufficient to indicate it continues to exist and our concerns regarding its impact on the quality of care in LTC facilities are well-founded. We believe that this demonstrates that change is necessary to ensure that all LTC consultant pharmacists are free from conflicts of interest, are able to base their professional medication recommendations on the best interest and clinical needs of LTC facility residents, and are able to advocate for the Medicare beneficiary.

Comment: CMS received a large number of comments from advocates and advocacy organizations, long term care ombudsmen, LTC consultant pharmacists, and others supporting a requirement for LTC consultant pharmacists to be independent and noting that such a policy was needed and long overdue. These commenters asserted that independence is essential to ensure that drug regimen reviews are impartial and the consultant pharmacist is able to act as an advocate for the resident without fear of financial repercussions. A commenter agreed with an independence requirement, noting that removing the financial incentives between the consultant pharmacists and the LTC pharmacy would increase transparency.

CMS also received many comments opposing a requirement that would separate LTC pharmacy consulting from dispensing services. Many of these commenters claimed the requirement would be seriously disruptive, asserting that communication and collaboration between the dispensing pharmacy and the consultant pharmacist would be diminished, consultant pharmacists would be deprived of access to proprietary LTC pharmacy systems, data and other resources critical to the performance of consultant pharmacists' activities. Opposing commenters noted the requirement would also deprive consultant pharmacists of the significant advantages derived from pharmacy employment, including health, retirement and other benefits, and would increase costs to both the LTC facilities and consultant pharmacists. A significant number of these commenters expressed concern that independence would decrease the quality of patient care accordingly.

Many commenters requested that we finalize the requirement and not yield to those who argued against it. CMS received several comments from independent consultant pharmacists noting that, although others have argued otherwise, working independently has neither hindered access to residents' prescription or medical information, nor diminished the residents' quality of care.

Response: We appreciate these comments, as well as the concerns expressed by those commenters opposed to the requirement for independent consultant pharmacists. The comments supporting the independence requirement have sustained our concerns about conflict of interest and its impact on the quality of long term care. Also, the significant advantages associated with employment described in the opposing comments serve to highlight the strong influence such financial ties can exert on pharmacy-employed consultant pharmacists and reinforce the importance of an independence requirement to ensure unbiased medication reviews. As a result, we remain convinced of the need for changes to ensure that the consultant pharmacists' recommendations are based solely on the residents' best interests and clinical needs. However, we acknowledge that an independence requirement could be highly disruptive to the industry overall, including the LTC facilities and those consultant pharmacists with current industry affiliations, and would result in higher costs to the facilities and consultant pharmacists.

Comment: A few commenters claimed we do not have the statutory authority to impose an independence requirement. These commenters asserted that we cannot use the Secretary's authority under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act, because consultant pharmacist independence has no direct relationship to resident health and safety. Therefore, for us to require consultant pharmacists to be independent would require Congressional authorization.

Response: We disagree. We believe that the conflict of interest inherent in the employment relationship between a consultant pharmacist and an LTC facility's pharmacy undermines the ability of the consultant pharmacist to make unbiased medication recommendations that are solely in the best interests of the residents. Many of the comments previously discussed corroborate our belief. Recommendations made on other bases, such as those reflecting the financial interests of the consultant pharmacist or the consultant pharmacist's employer, pose health and safety risks for the residents. Even in those situations in which the consultant pharmacist is able to make unbiased medication recommendations because there are no pressures to do otherwise, if the drug regimen review quota established by the consultant pharmacist's employer is so high as to permit the consultant pharmacist to perform only the most perfunctory medication reviews, then resident health and safety are at risk.

Comment: Many commenters agreed with the definition of ''independence'' we indicated we were considering. Some commenters disagreed with the definition, indicating that consultant pharmacists should not be permitted to be employees of the LTC facility in order to avoid the potential conflict of interest inherent in an employment relationship. Other commenters requested that consultant pharmacists be permitted to affiliate with pharmaceutical manufacturers and distributors. These commenters argued that affiliations with these entities permit the exchange of scientific and educational information on topics, such as medications and product benefits and risks, and much of this exchange occurs at educational programs supported by the industry at professional meetings and trade shows. They noted that consultant pharmacists frequently serve on industry advisory boards and are engaged as speakers and researchers with industry financial support and contended that HHS Office of Inspector General guidance for pharmaceutical manufacturers and industry guidelines related to the healthcare professionals' decision-making provide sufficient oversight. One other commenter requested that we define the terms ''affiliates'' and ''affiliated.''

Response: We acknowledge that there may be potential conflicts of interest in an employment relationship between consultant pharmacists and LTC facilities, but note that both the LTC facility and its residents have a common interest in the facility meeting CMS standards for unnecessary drug use in the facility. We do not agree with the commenters who advocated that we allow consultant pharmacist relationships with pharmaceutical manufacturers and distributors. The relationships that these commenters describe cause us substantial concern, as we believe they represent a basis for the conflicts of interest that we seek to eliminate. We believe that consultant pharmacists who receive remuneration from pharmaceutical manufacturers/distributors for activities, such as research and speaking engagements or for serving on advisory boards, may be influenced by these relationships in the performance of their consultant pharmacist activities. Thus, if the consultant pharmacists' recommendations are to be based solely on the LTC residents' best interests, these affiliations should be prohibited.

Comment: We received many comments from those supporting the independence requirement for LTC consultant pharmacists as well as from those opposing it, noting that consultant pharmacist independence would not solve the entire problem of conflict of interest, because other agents contribute to drug overutilization and inappropriate drug use in LTC facilities. Contributors specifically cited by commenters were LTC facility medical directors, nurse practitioners and physician assistants and the residents' attending physicians. A few commenters noted that family members, influenced by pharmaceutical advertisements, could request antipsychotics as adjuncts for depression and the prescriber could accede to these requests. Other commenters noted the LTC facilities' role citing serious understaffing, high staff turnover, and the lack of specialized staff trained in meeting the needs of dementia patients as factors contributing to inappropriate drug use in LTC facilities. Another commenter observed that others also play a contributing role, noting that a considerable number of residents admitted into LTC facilities from their homes, hospitals, and assisted living facilities are already on potentially unnecessary drugs.

Many commenters pointed out that the ultimate decision regarding what medications to prescribe and whether to accept or reject a consultant pharmacist's recommendation lies with the physician. Therefore, the commenters asserted prescribers, not consultant pharmacists, should be held accountable for overuse or inappropriate use of drugs in LTC facilities. Commenters claimed LTC residents' physicians, as well as the facility's medical director, rarely see or examine the residents and medications are reordered without the physician reviewing the residents' condition. According to another commenter, if a resident's behavior problem escalates, such as in the case of a resident with dementia, facility staff would call the physician to increase the medication dosage, and the physician would commonly comply without seeing the resident. Several other commenters noted that prescribers, aware of potential bias, ignore the consultant pharmacists' recommendations due to uncertainty that the recommendations are in the residents' best interests.

Many of the commenters in opposition to the consultant pharmacist independence requirement noted that conflicts of interest pervade the LTC industry, affecting the facility (which imposes its own formulary requirement to contain costs for the drugs it covers), facility staff (who can encourage the use of chemical restraints to manage residents with behavioral problems), and the residents' physicians and LTC facility-based prescribers (who may have their own financial ties to the pharmaceutical industry). For these reasons, the commenters objected to a requirement that would single out only one group of actors that contribute to this problem. Several commenters recommended that we require that all clinicians in an LTC facility be independent, or that we at least consider the role of the physicians who prescribe medications when determining how best to solve the problem. Other commenters agreed with the independence requirement, but indicated that it was only a partial solution and a more comprehensive approach would be necessary to respond effectively to the whole problem.

Response: We appreciate the many comments noting that others in the LTC industry, including facility staff and residents' attending physicians, contribute significantly to overutilization. Commenters not only implicated others as contributing to overuse of drugs in LTC facilities, but also described other factors that contribute to the problem. Therefore, we recognize that requiring consultant pharmacists to be independent will not solve the entire problem. As a result of these comments, we are better aware that the independence requirement we specifically described in the October 11, 2011 proposed rule would disproportionately target consultant pharmacists and leave the other actors to continue to operate as they do currently. This suggests that, unless the industry on its own implements steps to curtail overutilization and inappropriate drug use in LTC facilities, we must consider requiring broader changes than independence only for consultant pharmacists and propose those changes in future notice and comment rulemaking.

Comment: Several commenters mentioned the recent investigations of nursing homes conducted by the California Department of Public Health which found that LTC consultant pharmacists failed to identify and report the misuse of antipsychotic medications in 90 percent of the cases identified by investigators as involving inappropriate and potentially lethal doses of these drugs. We also received comments from an LTC pharmacy reporting that over the past 5 years its consultant pharmacists have made over 700,000 recommendations to prescribers regarding antipsychotic drug use and that more than 99 percent were recommendations to reduce dosage, discontinue or question use or recommend monitoring for side effects. (We note this commenter did not provide information on whether these recommendations were followed.) Citing these data from the LTC pharmacy, another commenter noted that, if (as the level of antipsychotic drug use suggests) prescribers are ignoring the consultant pharmacist recommendations, it raises the question of the effectiveness of the drug regimen reviews. A commenter suggested that, over time, conflict of interest can diminish prescribers' confidence in the consultant pharmacists, eroding their effectiveness. This suggestion was supported in the comments of another who claimed that prescribers who have been practicing in LTC facilities are sensitive to the ethical conflicts faced by consultant pharmacists and are skeptical of their recommendations because of the prescribers' uncertainty as to whether the recommendations are in the residents' best interests.

Response: These comments and the data reported by the commenters suggest that the required monthly drug regimen reviews are not yielding the intended outcomes nor are they providing the expected beneficiary protections. If perceived conflict of interest has potentially eroded confidence in the recommendations of the consultant pharmacists that prescribers are ignoring them and the reviews have become merely perfunctory exercises, then we may consider changing the requirements in § 483.60(c) and explore alternative requirements and approaches. In determining whether a regulatory change is necessary, we will continue to evaluate the number of deficiency citations for unnecessary medication use and will monitor two new performance measures on the use of antipsychotics in LTC facilities. These new performance measures, based on resident assessment information reported in the Minimum Data Set (MDS 3.0), will reflect antipsychotic drug use by short-term stay and by long-term stay facility residents and will be available later in 2012 on the CMS nursing home compare Web site at *http://www.medicare.gov/NHcompare/home.asp.*

Comment: We received extensive comments expressing serious concerns about the level of overuse and inappropriate use of antipsychotic drugs in LTC facilities. A commenter stated that, ''On any given day, over 350,000 nursing home residents receive powerful antipsychotics, despite FDA warnings that the drugs increase the risk of death and studies that show the drugs do not work and have terrible side effects.'' Many commenters noted the vast majority of those receiving these drugs are residents with dementia who are being chemically restrained when there are safe, effective, and less expensive nonpharmacological methods to care for these residents. Another commenter stated that studies show that compassionate, person-centered care can minimize anxiety and depression and minimize the need for psychotropic medications.

Response: We share the grave concerns expressed by the commenters concerning the level of antipsychotic drug use in LTC facilities. We believe these comments also call into question the effectiveness of the consultant pharmacists' drug regimen reviews in curtailing the use and misuse of antipsychotic drugs, regardless of whether the ineffectiveness is caused by inadequate medication reviews by consultant pharmacists or prescribing physicians ignoring the recommended changes. As we indicated previously, we agree that consultant pharmacist independence will not solve the whole problem. Therefore, we challenge the entire LTC industry to do what is in the best interests of our most vulnerable beneficiaries and implement the necessary and appropriate changes to address this serious situation.

We expect that through the implementation of changes, such as placement of greater emphasis on the use of nonpharmacological methods of care as an alternative to pharmacological treatment for the behaviors associated with dementia, the industry will achieve substantial improvement in the appropriate use of these medications. Although not all non-pharmacological treatments are appropriate for all patients, some nonpharmacological interventions may have potential benefits for residents with the behavior symptoms associated with dementia, such as agitation or aggression, wandering and sleeping disturbances. These interventions include, for example, music therapy, massage therapy, behavior management techniques, and animal-assisted therapy.

Comment: A number of commenters offered recommendations for increasing transparency in order to address conflicts of interest issues in LTC facilities. Some commenters recommended that we require LTC facilities to separate contracts for LTC consulting services from contracts for other services, including drug dispensing, and require LTC facilities pay a fair market rate for consultant pharmacist services. Some commenters suggested either that we require consultant pharmacists to disclose to the facility any affiliations that would pose a potential conflict of interest or require consultant pharmacists to sign an integrity agreement. Several commenters recommended that LTC pharmacies ensure that consultant pharmacists are empowered to make independent judgments and affirm this in a statement to the facility. One commenter suggested that, should the implementation of a requirement for consultant pharmacists to be independent be delayed, we require consultant pharmacists to disclose their affiliations and potential conflicts of interest.

Response: We continue to believe that requiring independent consultant pharmacists is part of the right approach to address our concerns regarding conflict of interest and quality of care in LTC facilities. It is an approach that was strongly supported by some consultant pharmacists who confirmed our belief that LTC pharmacies do exert pressure on the consultant pharmacists in their employ to influence the medication recommendations. It was also supported by individual commenters, advocates and advocacy organizations, Part D plan sponsors and PBMs, and consultant pharmacist organizations. However, we acknowledge that others in the industry, including LTC facility staff and prescribers, are likewise implicated in the problem of overprescribing and inappropriate drug use. Thus, an independence requirement solely for consultant pharmacists would not solve overutilization and would single out one party, but leave the others to continue unaffected. We agree with commenters that the requirement would be highly disruptive to both LTC facilities and consultant pharmacists with current industry affiliations. Because the proposed requirement does not address the role of facility staff and prescribers in driving overutilization and inappropriate use, it is unlikely to result in substantially reducing these problems that would, in our view, outweigh the costs of industry disruption.

Comment: We received several comments that noted the lack of empirical evidence linking overutilization of drugs in LTC facilities to consultant pharmacists' possible conflicts of interest. Numerous commenters suggested that we study the recommendations, drug utilization and outcomes data for independent and pharmacy employed consultant pharmacists and many of these commenters also recommended that we consult with stakeholders to better define and scope the problem and formulate a more appropriate approach for addressing it.

Response: If, as suggested by other commenters, consultant pharmacist recommendations are rarely acted upon, this calls into question the very purpose of the consultant pharmacists' medication reviews. We expect the industry to demonstrate the value of these reviews to the LTC residents' quality of care. Therefore, we believe the industry should collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations. We expect some, if not all, of these data are already being collected and we recommend the industry work with such entities as the Pharmacy Quality Alliance (PQA) and other consensus gathering organizations, to develop performance measures to assess consultant pharmacist effectiveness. Further, since the consultant pharmacists are not the only group with responsibility for ensuring the safety and efficacy of care in the LTC facility, we expect the LTC provider and medical industry to also implement changes to address the problem of overuse and misuse of medications in LTC so that we will see inappropriate prescribing of all medications, but particularly antipsychotics, decrease. Should marked improvement not occur, we will use future notice and comment rulemaking to propose requirements to address our concerns. In determining whether marked improvement has been made, we will continue to evaluate the number of deficiency citations for unnecessary medication use and will monitor the two new performance measures on the use of antipsychotics in LTC facilities.

Comment: We received comments recommending that LTC pharmacies be required to disclose their rebates and several other comments recommending the elimination of manufacturer rebates to LTC pharmacies based on utilization.

Response: Although we agree that market-share-moving rebates may provide incentives that are not in the LTC residents' best interests, we believe that these suggestions are beyond the scope of this proposal, and we are not in a position to respond to these recommendations at this time.

Comment: Several commenters recommended a requirement that facilities use qualified professional consultant pharmacists for LTC consulting services and strictly enforce compliance with that requirement. Another commenter suggested that, as an alternative, we establish an audit or other oversight process to review and evaluate all medication changes recommended by LTC consultant pharmacists and all contractual agreements that pose potential conflict of interest risk.

Response: We appreciate these comments and will consider the recommendations in the process of future rulemaking on this issue. However, as noted above, we believe the LTC industry should collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations and we recommend the industry work with such entities as the PQA and other consensus gathering groups, to develop performance measures to assess consultant pharmacist effectiveness. Since the consultant pharmacists are not the only group with responsibility for ensuring the safety and efficacy of care in the LTC facility, we expect the LTC provider and medical industry to also implement changes to address the problem of overuse and misuse of medications in LTC so that we will see inappropriate prescribing of all medication.

Comment: Many commenters responded to our request for comment on permitting exceptions for unique situations involving minimal conflict of interest risk or waiving the independence requirement to permit other alternate approaches. Some commenters recommended that we grant no waivers or exceptions, arguing that there should be a level playing field and that no employment relationship was free from conflicts of interest. Other commenters agreed with allowing exceptions or waivers for alternate approaches for IHS/Tribal facilities and facilities in rural or other ''hardship areas''. Several commenters suggested we monitor the exception and waiver processes to ensure they are fair and equitable. Other commenters requested either exceptions or alternate approaches for facilities with in-house pharmacies, VA, and State Veterans nursing homes, and various other situations.

Response: We appreciate these comments and will consider them in the process of future rulemaking on this issue.

Comment: Several commenters recommended either coordination between consultant pharmacists' drug regimen reviews and medication therapy management (MTM) services in order to eliminate overlap/duplication between the two reviews.

Response: We agree that the potential overlap between the drug regimen reviews required in LTC and Part D MTM reviews could possibly result in conflicting reviews. As a result, in the provision on MTM in LTC facilities discussed elsewhere in this rule, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC facilities. We note such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and consultant pharmacists (or their intermediaries).

Comment: Several commenters recommended we establish a January 1, 2013 effective date, and other commenters requested either a delay in implementation or suggested a later effective date. Commenters provided recommendations for phasing in the requirement and for implementing the requirement initially as a demonstration program. Commenters also noted that these latter approaches would enable us to benefit from lessons learned and identify best practices for future implementation.

Response: We appreciate these comments, but, as discussed further later in this section, we are not finalizing this provision at this time.

Comment: We received numerous comments in response to our request for information concerning best practices in the conduct of drug regimen reviews. A few commenters suggested that we require consultant pharmacists be afforded adequate time for the monthly drug regimen reviews. Another suggested that we refer to the American Society of Consultant Pharmacists ''Guidelines for Assessing the Quality of Drug Regimen Review in Long Term Care Facilities'' which the commenter noted provides standards to evaluate the quality of the drug regimen review and to improve the process. Several other commenters asserted that establishing a specific rate would be inappropriate because the facility's case-mix could affect the rate. However, other commenters specified what they believed would be the optimal rate per day; the suggested rates varied from a low of 20 to a high of 64 per day.

Response: We appreciate the comments and suggestions and will use them to inform possible future rulemaking regarding the drug regimen review requirements.

Comment: Many commenters noted that the services performed by LTC consultant pharmacists are more extensive than the drug regimen reviews and include activities, such as destroying unused medications, checking storage areas, conducting exit conferences, providing in-service education to nursing staff, observing medication distribution, and attending meetings. Commenters stated all the full range of consultant pharmacist services need to be considered in evaluating the impact of any new requirements.

Response: We appreciate these comments and, as we indicated in the October 11, 2011 proposed rule, we will use them to inform possible future rulemaking regarding the LTC consultant pharmacist requirements.

As a result of considering the comments we received on this issue, we now believe a more targeted and less disruptive approach, at least initially, is warranted. We considered the possibility of finalizing several of the requirements recommended by these commenters to increase transparency around current contractual arrangements and incentives. We agree with the recommendation that LTC facilities pay a fair market rate for consultant pharmacist services; we note that the OIG has stated that provision of consultant pharmacists' services by LTC pharmacies at below market rates ''present[s] a heightened risk of fraud and abuse'' (*OIG Supplemental Guidance Program for Nursing Facilities,* 73 FR 56832, 56838, note 53, September 30, 2008). However, we do not believe it is within our statutory authority to require provision of such services at market rates. We also considered requiring that LTC facilities separately contract for consultant pharmacist services from other pharmacy services and that consultant pharmacists disclose to the LTC facility, the medical director, ombudsmen, and residents upon request any affiliations that would pose a potential conflict-of-interest risk.

However, due to the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553) and section 1871(a)(4) of the Act, and their respective requirements that a final rule be the logical outgrowth of a proposed rule, we believe that any such requirements cannot be finalized in this final rule with comment period, since we did not propose them initially. As a result, since a requirement for independent consultant pharmacists will not solve the entire problem, but would be significantly disruptive for much of the LTC industry, we are not finalizing this provision at this time. Instead, we are soliciting additional comments to help us determine a more comprehensive approach to eliminate overprescribing and the use of chemical restraints in LTC.

In the meantime, given our continuing conflict of interest concerns, we strongly encourage the LTC industry in general to voluntarily adopt the following changes to increase transparency: separate contracting for LTC consulting services from dispensing and other pharmacy services; payment by LTC facilities of a fair market rate for consultant pharmacist services; and disclosure by the consultant pharmacists to the LTC facility of any affiliations that would pose potential conflicts of interest; or the execution by the consultant pharmacists of an integrity agreement. We expect the industry to use this opportunity to collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations. We believe that LTC pharmacies may already collect some, if not all, of these data and would be able to work with such entities as the Pharmacy Quality Alliance (PQA) and other consensus gathering organizations, to develop performance measures to assess consultant pharmacist effectiveness.

Until the next opportunity for us to propose a regulatory change, we will closely evaluate the number of deficiency citations for unnecessary drug use and will monitor the two new performance measures to track the use of antipsychotics in LTC facilities and expect to see significant improvement. We will also continue to participate in a Department of Health and Human Services (DHHS) initiative focused on the use of antipsychotics for persons with Alzheimer's disease. As part of this effort, we are seeking to eliminate the inappropriate use of antipsychotic drugs in LTC facilities for residents with Alzheimer's disease through updated guidance on the use of these medications and stricter enforcement of current requirements. In partnership with the Alzheimer's Disease Education and Referral Center, we will work to better educate LTC facilities, prescribers and the resident's families. We believe that effort focused on eliminating the use of inappropriate chemical restraints for LTC facility residents with Alzheimer's disease may also serve to improve the quality of care for the LTC facility residents with the behavior symptoms associated with dementia.

Our expectation is that the industry will implement changes to address the problem and we will see inappropriate prescribing decrease. Should marked improvement in inappropriate utilization not occur, we will use future notice and comment rulemaking to propose requirements to address these concerns. After considering the public comments received, we are not finalizing this provision. However, we are soliciting further comment to assist us to better define the problem and frame a more comprehensive solution to address our concerns regarding medication management and quality in LTC. Specifically, we solicit comment related to the following three issues:

• *Enhancing medication management and the effectiveness of medication review.*

We noted in the previous comment summary and responses that many commenters pointed out that besides consultant pharmacists, other parties and factors contribute to overprescribing and inappropriate drug use in LTC facilities. These commenters charged that prescribers, including facility medical directors, nurse practitioners and physician assistants as well as the residents' attending physicians, are major contributors. Others described how pharmaceutical representatives and advertising, family members, and the LTC facility's understaffing, high staff turnover, and lack of specialized staff trained in meeting the needs of dementia patients contribute to the problem. We noted, too, that commenters questioned the effectiveness of the consultant pharmacists' medication reviews, charging that drug regimen review quotas were so high that the reviews had become perfunctory and that others had described how the review requirements were subverted. Other commenters suggested that the consultant pharmacists' recommendations were being ignored by prescribers due to their lack of confidence that the recommendations were in the best interests of the residents. As a result of these comments, we are not only aware that requiring consultant pharmacists to be independent will not solve the entire problem, but also that the drug regimen reviews may not be yielding the intended outcomes or providing the expected beneficiary protections, Therefore, we seek comment in response to the following questions:

++ What actions/steps should be taken to strengthen attending physician (and other prescribers) medication management and prescribing practices to ensure the best quality of care for the nursing home resident?

++ What is and should be the role of the nursing home medical director in overseeing the attending physician (or other prescribers) medication management activities?

++ What actions, if any, should the medical director take when attending physicians (or other prescribers) fail to engage in appropriate/adequate medication management activities?

++ What actions/steps could be undertaken to establish and ensure the independence and effectiveness of a consultant pharmacist in conducting their medication reviews on behalf of nursing home residents?

++ What training and best practice models would assist all nursing home staff to better understand behavior signs and symptoms and respond appropriately and effectively in assisting and caring for nursing home residents?

• *Data collection and use.*

As we indicated previously, in commenting on this provision, several commenters noted the lack of empirical evidence linking overuse and inappropriate use of drugs in LTC facilities to consultant conflict of interest. Numerous commenters recommended CMS conduct further study and consult with stakeholders to better define the problem and formulate a more appropriate approach for addressing it. As a result, we solicit comment in response to the following questions:

++ What data are needed to enable and support the Medicare and Medicaid programs and others in monitoring the appropriateness and adequacy of medication management activities, including the use of antipsychotics drugs?

++ What data are needed to enable CMS to study the effectiveness of consultant pharmacist medication reviews?

++ What data are needed to create public performance metrics regarding the independence of consultant pharmacists and prescribers from pharmacies and drug manufacturers/distributors?

++ Are data needed on the number and type of interventions recommended by consultant pharmacists and on the outcomes of those recommendations? If so, how could such data be used and by whom?

• *Increasing transparency.*

Finally, as noted previously, a number of commenters offered recommendations for increasing transparency in order to address conflict of interest in LTC. Many commenters on this provision charged that conflict of interest was pervasive in LTC, affecting the facility which imposed its own formulary requirements to contain costs for the drugs it covered, facility staff who encouraged the use of chemical restraints to manage residents with behavioral problems, and residents' attending physicians and facility prescribers who may have had their own ties to the pharmaceutical industry. We expressed our interest in several of the recommendations, but due to the notice and comment provisions of the Administrative Procedure Act and section 1871(a)(4) of the Act, and their respective requirements regarding logical outgrowth, we believe that any such requirements cannot be finalized in this rule. Thus, we solicit comment in response to the following questions:

++ What specific details regarding the financial (and other) arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services should be disclosed, and to whom should this information be available?

++ Should the public be informed of the financial and other arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services? If so, what metrics could be used?

++ What information is needed to assess the independence and adequacy of physician (and other prescriber) medication management and oversight on behalf of nursing home patients? What metrics could be used to assess the adequacy and appropriateness of prescriber response to consultant pharmacist recommendations?

++ What metrics could be used to describe the adequacy and appropriateness of a LTC facility's medication management program?

++ Describe the incentives and other arrangements that create the conflict of interest in LTC that contributes to overutilization and inappropriate drug use in LTC facilities. How can the conflict of interest stemming from these incentives and arrangements be contained or eliminated?

C. Excluding Poor Performers

We are finalizing three proposals designed to strengthen our ability to remove poor performers from participation in the Part C and D Medicare programs. Beneficiaries will be protected through the first provision, which enables CMS to terminate or non-renew any health care prepayment plan (HCPP) which does not adhere to specified financial, reporting, and access requirements.

The next two regulatory changes we are finalizing give entities that want to administer benefits to Medicare beneficiaries strong incentives to pay attention to the star rating criteria and provide for better quality health care if they wish to stay in or join the program. See Table 4 for details of these proposals. Specifically, we are finalizing a regulation which will provide CMS the authority to terminate MA organizations and Part D sponsors that have failed to achieve, over a period of 3 years, at least a 3-star plan rating. This authority will enable us to utilize the plan rating system, which we developed to provide beneficiaries with information about the quality and performance of health and drug plans to assist in plan selection during the open enrollment period. The plan ratings include process measures that focus on whether good medical care or drug care was provided, outcome measures that address the result of that care, and measures that relate to administrative processes that support and direct the provision of care. It is our view that the star rating system not only provides beneficiaries/consumers with easy-to-understand information critical for making choices among sponsors, but provides a powerful tracking tool that enables us to continue to administer the Part C and D programs with the best interests of the beneficiaries in mind.

We are also finalizing a regulation that provides CMS the authority to deny applications submitted by MA organizations and Part D sponsors that have performed so poorly that CMS has terminated or non-renewed a contract with the organization in the past. We anticipate that this regulation will directly enable us to protect beneficiaries from poor care.

TABLE 4—PROVISIONS TO EXCLUDE POOR PERFORMERS

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.C.1	CMS Termination of Health Care Prepayment Plans.	Subpart U	417.801	N/A	N/A	N/A	N/A
II.C.2	Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract.	N/A	N/A	Subpart K	422.504 422.510	Subpart K	423.505 423.509
II.C.3	Denial of Applications Submitted by Part C and D Sponsors with a Past Contract Termination or CMS-Initiated Non-Renewal.	N/A	N/A	N/A	422.502	Subpart K	423.503

1. CMS Termination of Health Care Prepayment Plans (§ 417.801)

Section 1833(a)(10)(A) of the Act authorizes arrangements with HCPPs, but specifies only what type of benefits are to be provided (Part B), the method of payment (reasonable cost), and limits on cost-sharing (20 percent of reasonable cost). In implementing section 1833(a)(1)(A) of the Act, we have in regulations set forth requirements relating to these three areas that parallel those imposed under section 1876 cost contracts. In addition, since section 1833(a)(1)(A) of the Act does not address appeals, and the appeals procedures in section 1869 of the Act involve specific claims payments that do not exist for HCPP enrollees, in our January 2005 final rule (70 FR 4588 through 4741), we extended fundamental features of the MA appeals process to HCPPs.

Although our current regulations at § 417.801(d) permit us to terminate a contract with an HCPP for specified reasons, we proposed to codify additional specified grounds for HCPP termination in § 417.801(d) to strengthen our oversight and enforcement capabilities. Section 417.801(d) currently provides that we may terminate or not renew a contract with an HCPP if the HCPP: (1) No longer meets the requirements for participation and reimbursement as an HCPP; (2) is not in substantial compliance with the provisions of the agreement or applicable statutory or regulatory requirements; or (3) undergoes a change in ownership. We proposed to retain these bases for termination but to modify § 417.801(d)(ii) to include three specific circumstances in which ''substantial non-compliance,'' that relate to the CMS contract, applicable CMS regulations, or applicable provision of the Act may be found. As we stated in the proposed rule, we believe that specifying instances of substantial non-compliance through notice-and-comment rulemaking will ensure that all HCPPs are aware that their failure to comply with such requirements may lead to termination of their contracts.

First, in their agreements with us, HCPPs agree to provide adequate access to providers and to document such access. Accordingly, we proposed that failure to provide adequate access to providers, and provide CMS with documentation of such access, is a basis for determining that an HCPP is not in substantial compliance with applicable regulatory requirements. We proposed to expressly identify this violation as an adequate justification for termination or non-renewal in a new paragraph (d)(1)(ii)(A). Second, HCPPs are required to provide data to us and to maintain financial records and statistics related to costs payable by CMS for CMS audit or review. This requirement is currently captured in § 417.806, which cross references financial records requirements at § 417.568 of the section 1876 cost contract plan regulations. We stated in the proposed rule that we would specify, in new paragraph (d)(1)(ii)(B), that failure to provide such data and/or to maintain records appropriately is another violation indicating that an HCPP is not in substantial compliance. Third, HCPPs must report costs to us in addition to maintaining financial records and following other financial requirements specified at § 417.568 of the cost contract program regulations. Currently, these requirements are also referenced in HCPPs' agreements with CMS. We proposed that a new paragraph at (d)(1)(ii)(C) would specify that failure to report costs to CMS will constitute yet another basis for determining that an HCPP is not in substantial compliance.

Comment: A commenter supported the provision as specified in our proposed rule.

Response: We thank the commenter for their support.

After consideration of the public comment received, we are finalizing the policy without modification. We would also clarify that this new list is not exhaustive and CMS may still make a determination that a HCPP is not in substantial compliance absent the existence of any of these individual violations.

2. Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§ 422.504, § 422.510, § 423.505, and § 423.509)

Since 2007, we have developed and published annual performance ratings for all stand-alone Medicare PDPs. In 2008, we began issuing ratings for MA plans as well. The ratings are based on measures that address a range of health and drug plan performance categories, including access to care, communication with members, and clinical quality of care. The scores in each performance category are based on data reported by MA organizations and PDP sponsors, member satisfaction, and monitoring conducted by CMS and its contractors. We rate MA organizations and Part D sponsors on a 5-star scale, with the best performers receiving a rating of 5 stars. The organizations receive a score for each performance measure, a summary score each for Part C and Part D, as well as an overall rating. Under the methodology developed and applied by CMS for its star rating process, a rating of 3 or more stars is an indication of sponsors with ''average'' or better performance. By contrast, organizations receiving a summary or overall score below 3 stars are among the weakest performers in the Medicare Part C and D programs.

The Medicare regulations at § 422.503(b)(4) and § 423.504(b)(4) state that, to qualify as an MA organization or Part D sponsor, an organization must have administrative and management arrangements satisfactory to CMS, including, per § 422.503(b)(4)(ii) and § 423.504(b)(4)(ii), personnel and systems sufficient for the organization to implement, control, and evaluate the activities associated with the delivery of Part C and D benefits. Once under contract with CMS as an MA organization or Part D sponsor, an organization remains obligated to maintain satisfactory administrative and management arrangements, a point we proposed to clarify by adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) to the list of required elements in CMS' contracts with MA organizations and Part D sponsors. Also, as explained later in this section, we believe that the plan ratings are a direct indicator of the ongoing effectiveness of a contracting organization's administrative and management arrangements. Therefore, we proposed adding paragraphs § 422.504(a)(18) and § 423.505(b)(26) to require an organization to demonstrate that it maintains satisfactory administrative and management arrangements by achieving a summary plan rating of at least 3 stars each year.

We also proposed to establish the failure to achieve a 3-star summary rating consistently as a basis for contract termination. As the measures in the star ratings are based largely on Part C and D program requirements, and the plan ratings are a reflection of a sponsor's performance across a range of program areas, we believe that a sponsor with a low Part C or Part D summary star rating has failed in a significant way to meet its obligations as an MA organization or Part D sponsor. (As we calculate the summary rating score by taking an average of the measure-level stars, sponsors can receive scores on individual measures of less than 3 stars but still achieve a summary rating of at least 3 stars.) A sponsor that fails to achieve at least an ''average'' rating for 3 consecutive years has demonstrated consistently that it is unable or unwilling to take corrective action to improve its Part C or D performance.

As noted previously, to qualify as an MA organization or Part D sponsor, an organization must have effective administrative and management arrangements. Such arrangements involve the allocation and coordination of an organization's resources to ensure that it can fulfill the entire range of its obligations related to the delivery of Medicare benefits. Of course, the importance of these arrangements only increases once an organization has entered into an MA organization or Part D contract as the quality of the arrangements is tested repeatedly by the process of actually delivering Medicare benefits in a timely and effective manner during the term of the contract. Because of the critical role administrative and management arrangements play in ensuring an organization's compliance with its Medicare obligations, we believe it is necessary to make clear, by adding to the set of required CMS contract elements, that organizations must continue to maintain effective administrative and management arrangements even after they have entered into Medicare contracts. Accordingly, we proposed adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) which state that the maintenance of effective administrative and management arrangements is a material term of the MA organization and Part D sponsor contracts. The summary rating for a plan sponsor is calculated according to the methodologies outlined in the Plan Star Ratings technical notes, and is based on a formula that factors in a sponsor's scores on all measures pertaining to Part C to calculate the Part C summary rating and pertaining to Part D to calculate the Part D summary rating. (The Part C and D technical notes may be found on the CMS Web site at *https://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp.*) Organizations that offer both Part C and Part D benefits receive an overall rating that combines the Part C and D star ratings results. To evaluate an organization's administration and management capabilities accurately, it is necessary to review its performance across a range of operational areas. Because the summary Plan Rating scores are based on a sponsor's performance of a wide range of Medicare requirements within each of the MA and Part D programs, the scores are a reliable measure of the quality of an organization's administrative and management arrangements. Therefore, to articulate the standard by which we would measure compliance with that obligation, we proposed to establish as a requirement that organizations must achieve a summary plan rating of at least three stars for each of Part C and Part D each year by adding paragraphs § 422.504(a)(18) and adding paragraph § 423.505(b)(26). It would not be appropriate to use the overall rating for this purpose, as organizations that offer both Part C and Part D benefits must fully meet the requirements of each program independently. It is conceivable that if we exclusively rely upon the overall measure, strong performance within one program could mask poor performance in the other program, which would not be an acceptable outcome thus giving CMS an inaccurate picture of the effectiveness of a sponsor's administrative and management arrangements.

The star ratings may also be used as a basis for contract enforcement actions (for example, termination/non-renewal or intermediate sanctions). We have the authority under section 1857(c)(2) of the Act to terminate CMS' contract with an MA organization or a Part D sponsor when we determine that the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the Part C or D programs. A summary rating of less than 3 stars can be achieved only when a sponsor demonstrates poor performance across a range of measures. Therefore, we believe that sponsors that consistently achieve poor plan ratings have demonstrated a substantial failure to comply with the terms of their Medicare contracts. Also, low-rated sponsors interfere with the efficient and effective administration of the MA and Part D programs as beneficiaries rely on us to ensure that the array of plan choices only includes offerings from sponsors that have demonstrated that they can provide at least ''average'' or better quality services to their members.

Accordingly, we proposed to amend the bases upon which CMS may terminate an MA organization or Part D sponsor contract under § 422.510(a) and § 423.509(a) to include a sponsor's failure to achieve at least a 3-star summary plan performance rating for 3 consecutive contract years. We believe that 3 years is sufficient time for a sponsor to develop and implement corrective action and for improved performance to be reflected in the star ratings issued at the conclusion of the 3-year period.

We base our determinations that good plan ratings are indicative of the strength of an organization's administrative and management arrangements and that consistently poor plan ratings are a basis for contract termination on the fact that the elements of the plan ratings correlate to Part C and D requirements described in applicable statutes and regulations. While the exact measures may vary slightly from year to year, each year's plan ratings are based on similar elements from previous years, as they are developed in consultation with a workgroup of industry stakeholders and based on a review of stated Part C and D program requirements. The plan ratings issued in September 2010 (referred to as the CY 2011 plan ratings) provide a useful template for demonstrating the correlation between program requirements and the performance measured. (See 2011 Part C Technical Notes and 2011 Part D Plan Ratings Technical Notes: September 2010.)

The CY 2011 Part C plan ratings were organized into five domains—''Staying Healthy: Screenings Tests, and Vaccines;'' ''Managing Chronic (Long Term) Conditions;'' ''Ratings of Health Plan Responsiveness and Care;'' ''Health Plan Members' Complaints and Appeals;'' and ''Health Plan Telephone Customer Service.'' The Part C regulations at § 422.152(a)(2) state that MA organizations must conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction and address areas identified by CMS. The Staying Healthy measures evaluated the extent to which MA organizations provided screenings to their members for conditions such as breast cancer, colorectal cancer, elevated cholesterol, glaucoma, and osteoporosis, as well as monitoring to patients with long term medication and flu vaccines to plan members. As these measures have been consistently included in the Part C plan ratings over a period of several years, it is fair to say that MA organizations have known over that same timeframe that we would rate them on quality improvement projects designed to address the identified conditions and that they should take action to improve their scores for this measure. Moreover, we have clearly fulfilled our obligation under § 422.152(a)(2) to identify areas that MA organizations need to address for this purpose by annually publishing the methodology, providing private previews for MA organizations to review their own results, and releasing the results publicly through the CMS Web site. As a result, an MA organization's score in the ''Staying Healthy'' domain is a fair measure of the extent to which it is complying with § 422.152(a)(2).

The ''Managing Chronic (Long Term) Conditions'' domain most closely mirrors the requirements at § 422.152(a)(1) which obligate MA organizations to have a chronic care improvement program that addresses populations identified by us based on a review of current quality performance. The measures in this domain concern the management of conditions such as osteoporosis, diabetes, and high blood pressure. Again, the measures have remained largely constant for a number of years, so MA organizations have had effective notice that we had identified beneficiaries with those conditions as the populations for which we would expect sponsors to implement effective chronic care improvement programs. The measures related to the ''Health Plan Responsiveness and Access to Care'' domain demonstrate an MA organization's compliance with its obligations under § 422.112(a)(1) to maintain a provider network sufficient to ensure its enrollees' access to covered services. The measures ''Getting Needed Care'' and ''Getting Appointments and Care Quickly'' are both based on the results of beneficiary surveys concerning their experiences in being able to get timely appointments with plan-contracted providers. The measure ''Doctors Who Communicate Well'' reflects enrollees' responses to a series of questions concerning the quality of their interaction with plan-contracted physicians, including the amount of time the physicians spent with an enrollee and the care with which the physicians conducted appointments, all of which indicate the extent to which those services are provided in a manner consistent with professionally recognized standards of health care, per § 422.504(a)(3)(iii).

In the ''Health Plan Member's Complaints and Appeals'' domain, we provide a rating of the extent to which an MA organization affords its members their coverage determination appeal rights under the Part C program. The Part C regulations at Part 422, Subpart M, require MA organizations to adhere to standards and timeframes for issuing timely and accurate determinations concerning the coverage of health services for their members as well as the processing of their appeals of such determinations. The ''Makes Timely Decisions about Appeals'' rating measures the extent to which an MA organization meets the regulatory deadlines for issuing responses to member appeals while the ''Reviewing Appeals Decisions'' rating measures the frequency with which the MA organization determinations were overturned by the Independent Review Entity (IRE). The analysis for these measures was conducted by Maximus, Inc., with which we contracted as an IRE for Part C appeals. The remaining measures under this domain, ''Complaints about the Health Plan'' and ''Corrective Action Plans'' (CAPs) provide a more general view of an MA organization's performance from two different perspectives. The ''Complaints'' measure is based on a calculation of the rate (that is, complaints per 1,000 members) at which we receive complaints from beneficiaries, providers, or others affected by the MA organization's operations. The CAP measure reflects the number and type of findings made by us during an audit of an MA organization's performance. Thus, these two measures provide a snapshot of the MA organization's compliance with a range of requirements from the perspective of the members it must serve as well as CMS.

The ratings in the last Part C domain, ''Health Plan Customer Service,'' are the product of a series of measures related to the requirement that MA organizations operate a customer service call center that is responsive to the needs of Medicare beneficiaries. In particular, the domain rating is based on the results obtained by a CMS contractor that conducts test calls to MA organization customer service lines to assess the extent to which the call centers provide accurate plan information, in languages spoken by beneficiaries residing in the plan's service area, and with limited hold times consistent with the standards stated in the Medicare Marketing Guidelines we have issued pursuant to § 422.111(g).

The four domains of the CY 2011 Part D Plan Ratings similarly correspond to the requirements with which Part D plan sponsors must comply. The Part D domains are ''Drug Plan Customer Service;'' ''Drug Plan Member Complaints and Medicare Audit

Findings;'' ''Member Experience with the Drug Plan;'' and ''Drug Pricing and Patient Safety.'' The domain ''Drug Plan Customer Service'' includes measures concerning hold times, accuracy of information, and foreign language interpretation services and are the Part D equivalents of the measures used in the Part C plan rating. They reflect the Part D sponsor's compliance with the customer service call center requirements described in the Medicare Marketing Guidelines issued in accordance with § 423.128(d)(1). The measure related to hold times for pharmacists' calls to the sponsor are evidence of the sponsor's compliance with the requirement, stated at § 423.128(d)(1) that the sponsor operate a call center to provide technical assistance to pharmacists concerning their plan operations. This domain also contains three measures related to plan performance of its obligations related to the issuance of coverage determinations and processing of members' appeal requests, per Part 423, Subpart M. The last measure in this domain indicates the extent to which a sponsor is complying with CMS processes for ensuring that the data used by pharmacists to determine a customer's Part D plan enrollment is accurate and up to date. The provision of this data, referred to as ''4Rx data'' is part of Part D sponsors' obligation, stated at § 423.505(b)(2), to process enrollments in a manner consistent with the requirements stated in Part 423, Subpart B.

The second domain, ''Drug Plan Member Complaints and Medicare Audit Findings,'' consists largely of the same kind of measures related to beneficiary satisfaction and CMS audit findings as included in the Part C plan ratings, and the discussion provided above of their bearing on a determination of a sponsor's compliance with program requirements is applicable to the Part D ratings as well.

The ''Member Experience with Drug Plan'' domain consists of measures related to plan members' experience in getting access to information about their Part D plan or getting prescriptions filled easily when using the plan. These measures provide evidence of a sponsor's compliance with the requirement, stated at § 423.128, that it disseminate information about its Part D plans, and that it provide benefits through a point of claims adjudication system (per § 423.505(b)(17)) operated through a contracted pharmacy network that meets Part D access requirements (per § 423.120).

The ''Drug Pricing and Patient Safety'' domain consists, in part, of measures related to a sponsor's ability to maintain and transmit accurate information related to its members' LIS eligibility status and the information concerning drug prices available at network pharmacies. Under this domain, CMS assesses, by comparing its data with that of Part D sponsors, the accuracy of a sponsor's records concerning the LIS status of its members a significant part of its obligation under § 423.800 to participate in the administration of the low-income subsidy portion of the Part D benefit program. With respect to drug pricing, we compare sponsors' data reported to us, pursuant to § 423.505(f)(2), with other data sources, including prescription drug event data and data from commercially available drug pricing reference files. The remaining two measures in this domain assess the sponsor's efforts to ensure that its members are being directed away from drugs with a high risk of side effects and that those members with diabetes are treating their high blood pressure with medication appropriate for their condition. Both of these measures are indications of a sponsor's compliance with its obligation under § 423.150(c) to develop and implement drug utilization review systems that identify patterns of inappropriate care among its enrollees.

The thresholds we have established for the star ratings in each category are based on regulatory standards or our review of industry performance over several years. From that systematic review, for each regulatory standard-based measure we consider the actual contract scores in relation to a theoretical distribution of all possible measures with the regulatory standard considered a 3-star rating. (For example, in 2008 CMS announced to Part D sponsors that, after a review of industry performance during the first 2 years of the Part D program, we had established that sponsors would be required to submit 4Rx data for 99 percent of their enrollment transactions to be considered compliant with Part D enrollment processing requirements.) When an absolute performance standard has not yet been established, we assign stars for measures based on evaluating the maximum score possible for that measure, and testing initial percentile star thresholds with the actual data. The contract-level scores are grouped using statistical techniques to minimize the distance between scores within a grouping (or ''cluster'') and maximize the distance between scores in different groupings. Most databases that are utilized are not normally distributed, requiring further adjustments to the star thresholds to account for gaps in the data. CMS does not force the Plan Ratings data into 5-star categories for every measure. For some measures, based on the distribution of the data, there may only be 3. 4, or 5 stars, while for other measures there may only be 1, 2, or 3 stars. In developing that methodology, we reserved 1- and 2-star ratings for performance that was significantly below what a review of industry-wide performance would show to be acceptable and achievable by competently administered sponsors. This establishment of compliance standards through the analysis of all Medicare contractors' performance to identify outliers is consistent with our regulatory authority at § 422.504(m)(2) and § 423.505(n)(2). We have previously issued guidance (for example, CY 2012 Call Letter, page 119, issued April 4, 2011) to MA organizations and Part D sponsors indicating that we considered organizations with 3 consecutive years of less than 3-star Plan Ratings to be out of compliance with Medicare program requirements. We stated there that organizations with such a Plan Rating history should expect that, prior to initiating a termination action, we would confirm that the data used to calculate the Plan Ratings did reflect an organization's substantial failure to comply with Part C or D requirements. In essence, we noted that poor Plan Rating scores were a strong indication, but not conclusive evidence, of substantial non-compliance. In applying that policy, we include Plan Ratings issued in years prior to the issuance of the guidance to identify organizations whose performance may warrant contract termination.

With the elevation of low Plan Ratings from the status of likely indicator to conclusive evidence of substantial non-compliance, we believe that the use of prospective Plan Ratings is more appropriate in our application of this authority. Therefore, we proposed that we would not begin calculating the 3-year period until after organizations have received notice through the rulemaking process of the new basis for contract termination. As we plan on this proposal to be issued as part of a final rule in the spring 2012, we expect to use only those Plan Ratings issued after the publication of the final rule. That is, we would use the contract year 2013 Plan Ratings, which we expect to issue in September 2012, as the first set of ratings in the calculation of any sponsor's 3 consecutive years of Plan Ratings. The issuance of the 2015 ratings, expected in September 2014, will present the first opportunity for sponsors to have accumulated three consecutive years of low plan ratings that could subject them to contract termination. We invited public comment on our proposal for identifying the first set of Plan Ratings we would use in determining whether a sponsor's performance during 3 consecutive years supported a CMS decision to terminate its Medicare contract.

Comment: Several commenters expressed opposition to the proposed addition of the failure to achieve 3 stars for 3 consecutive years to the list of bases upon which CMS may terminate an MA organization or PDP sponsor contract. They maintain that the plan rating system is not sufficiently mature or stable to provide a reliable basis for determining that an organization has substantially failed to comply with its contract. The commenters maintain that the number and type of measures have changed each year that CMS has released plan ratings. These annual changes undermine the proposed termination authority in two ways. First, the variable measures and weighting over a 3-year period mean that CMS cannot fairly evaluate a sponsor's plan rating performance over 3 years because it has not applied a consistent standard of review during that period. Second, low-rated sponsors' efforts to take corrective action to raise their ratings over 3 years are impeded by CMS' annual changes to its methodology for calculating those ratings.

Response: The Medicare plan rating system and its component measures have been in place for a sufficient period of time for plan sponsors to become familiar with the correlation between their operations and the plan ratings they have achieved. MA organizations have been measured on a star system since 2008 and Part D plans since 2007. In addition, the vast majority of measures, which come from HEDIS and CAHPS, have been required of MA organizations since the late 1990s.

While we have made some changes in each of the past 3 years to the plan rating methodologies, these changes have been relatively minor and have not affected sponsors' ability to achieve and maintain at least a 3-star summary rating over a 3-year period. This history suggests that organizations have had ample time to adjust their efforts toward achieving higher quality outcomes. For the 2010 Part C ratings through the 2012 ratings, 30 of the measures remained constant, while the 2010 ratings featured a total of 33 measures, 37 in 2011, and 36 in 2012. For the Part D ratings during the same period, 13 measures remained constant, out of 19 total in 2010 and 2011 and 17 total for 2012. We have also made low-rated sponsors aware, through the issuance of compliance notices beginning in 2010, of the risk their low plan ratings pose to their status as Medicare Part C and D sponsoring organizations and the urgent need for them to take corrective action.

Comment: Several commenters expressed their strong support for the proposed provision. They also suggested ways to strengthen the termination authority by making it effective immediately upon publication of the final rule rather than after the release of the CY 2015 plan ratings in late 2014 as we had proposed. They also recommended that any reinstatement of a sponsor's contract be accompanied by a probationary period during which the sponsor's contract could be terminated if it fails in one year to achieve a 3-star rating. The commenters also urged CMS to apply our existing sanction and termination authority against low-rated plans, improve outreach to beneficiaries about the meaning and usefulness of the plan rating system to encourage their participation in HEDIS and CAHPS surveys, and to conduct ongoing evaluations of performance measures to make sure they truly drive improvement in areas important to beneficiaries.

Response: We appreciate the expressions of support for our proposal. We also appreciate the advocates' recommendation that we strengthen the termination authority, but we believe that our draft provision allows for a reasonable transition period during which sponsors can take steps, in light of the increased consequences of low plan ratings (that is, contract termination), to focus their attention and resources on quality improvement. Of course, as we have stated in recent call letters, during the transition period (that is, from the date on which this rule becomes final until CMS' publication of the CY 2015 plan ratings in late 2014) we will continue to apply a heightened scrutiny to consistently low rated contracts to determine whether they are substantially failing to meet Part C or D program requirements.

We appreciate the concern expressed by the commenters that sponsors that re-enter the Part C and D programs after a termination for consistently low plan ratings not be permitted to ''game'' the system by immediately repeating their previous poor level of performance. We believe, however, that our proposal already provides a sufficient safeguard against that type of conduct without requiring re-entering sponsors to operate under a probationary period during which even one year of poor performance would be a sufficient basis for termination. In section II.C.3. of the proposed rule, we stated our intent to adopt the regulatory authority to disapprove an application for qualification as a Part C or D contract submitted by an organization for which CMS had terminated a Medicare contract within the previous 3 years. This authority, which we finalize in this rule, will apply to all terminated sponsors, including those terminated based on consistently low plan ratings. We believe the 3-year period of ineligibility for Part C or D program participation, combined with the forfeiture of their entire set of plan members, is sufficient to provide an incentive for returning sponsors to achieve 3-star ratings upon their return to the Medicare program. We also note that consistently low plan ratings will not become the exclusive basis for contract termination. We retain the authority to terminate a sponsor based on its performance within only one year if its performance during that period fails substantially to meet Medicare requirements, and we will exercise that authority where justified.

The comments concerning outreach to beneficiaries discussing participation in the survey tools whose results are used to calculate plan ratings are outside the scope of this proposal. We believe this is also true of the comments concerning the need for CMS to continue to review plan rating measures to make certain they truly evaluate plan quality. We nonetheless agree that these efforts will receive our continued attention.

Comment: Several commenters suggested that Congress did not intend for the plan ratings to be used as a basis for contract termination. One commenter also stated that the plan rating system was not designed to measure compliance, and it is more effective as a plan comparison and beneficiary education tool.

Response: While the plan ratings were originally developed by CMS as a beneficiary comparison tool, and Congress has authorized the awarding of bonus payments based on plan rating performance, those facts do not preclude the use of plan ratings as an indicator of contract compliance. To the extent that the ratings provide reliable evidence of compliance with program requirements, they may be used as a basis for contract termination. Our preamble discussion in the proposed rule and this final rule with comment period describes the connections between each plan measure and a Part C or D requirement, noting that the measures are an effective tool for capturing information on the effectiveness of a sponsor's administrative and management arrangements as opposed to whether the arrangements are merely in place. Thus, a sponsor's failure to meet minimal performance thresholds for 3 straight years can reasonably be said to be evidence of substantial failure to meet contract requirements.

Comment: A stand-alone PDP sponsor commented that Part D sponsors are not required by statute to ensure their members' compliance with oral diabetes, hypertension, and cholesterol medication regimens. The commenter also noted that CMS announced the measures related to drug regimen compliance too late in the year for sponsors to focus their efforts on the new measures. Finally, the commenter stated that PDP sponsors are at a disadvantage in these measures because they do not coordinate care with prescribers as health plans can.

Response: All Part D sponsors are required to administer medication therapy management programs, which may be focused on beneficiaries with diabetes, hypertension, or high cholesterol. We agree that sponsors would have benefitted from an earlier announcement of the new measures, but we believe that the 3-year phase in of the plan rating-based termination authority will give PDP sponsors sufficient time to make improvements to their performance in these areas. Also, according to our plan rating methodology, a high score on these three measures is not critical to achieving a 3-star summary plan rating. Therefore, these measures do not impose a meaningful obstacle for PDP sponsors to maintain the required minimum plan rating.

Comment: A law firm that represents clients in Medicare-related matters commented that CMS does not have the authority to impose a conclusive presumption of a basis for contract termination when doing so eliminates the affected sponsor's opportunity for a hearing prior to the termination taking effect. The commenter also asserted that the use of plan ratings as a basis for termination would relieve CMS of its statutory obligation to prove that the sponsor's conduct has met the statutory criteria for contract termination and presented a regulatory construct analogous to that struck down by the U.S. Supreme Court in *Ragsdale* v. *Wolverine World Wide, Inc.,* 535 U.S. 81 (2002). Finally, the commenter stated that the proposed termination authority violates the requirements of the *per se* rule as discussed by the Court in *Johnson* v. *California,* 543 U.S. 499 (2005) and *Arizona* v. *Maricopa County Medical Society,* 457 U.S. 332 (1982).

Response: The new termination authority as finalized in this rule has no impact on the administrative appeal rights currently afforded any plan sponsor under Subpart N of 42 CFR Parts 422 and 423.

We do not find the Supreme Court opinions cited by the commenter to be applicable in any way to our proposal. In *Ragsdale,* the Court held that the Department of Labor could not enforce regulations that had the effect of eliminating one of the elements that an individual must prove when appealing a denial of leave from work requested under the Family and Medical Leave Act. Our use of low plan ratings as a basis for contract termination does not relieve us of our obligation to prove at least one of the three statutory bases for termination. Rather, the plan ratings are a tool that we will use to establish, consistent with the Part C and D statutes, that a sponsor has substantially failed to meet the requirements of its Part C or D contract. As noted previously and in the proposed rule, the data used to calculate the plan ratings are derived directly from a sponsor's performance of its Medicare program obligations.

The *Johnson* and *Arizona* opinions are similarly inapplicable to the proposed termination authority. The *Johnson* matter was a civil rights case involving the California Department of Corrections' (CDC) policy of segregating inmates by race. The Court there held that the lower courts should use strict scrutiny in reviewing whether the CDC policy violated prisoners' rights under the Equal Protection Clause of the 14th Amendment. The majority opinion of the Court makes no reference to a *per se* rule or to any set of criteria governing its use. The opinion involves an analysis of the law as it applies uniquely to allegations of racial discrimination and cannot be said to provide any framework for the analysis of the contract termination process in the Medicare program. *Arizona* is an antitrust case where the Court's majority opinion provides a discussion of the meaning of the *per se* rule as it applies to price fixing agreements (that is, certain practices are deemed to violate antitrust law without regard to surrounding circumstance or intent). The opinion provides no principles for assessing the legality of *per se* rules in general, nor does it state that the legitimacy of a *per se* rule is dependent on the maintenance of the exact same evaluation standards from year to year, as the commenter maintains.

Comment: Several commenters noted that plan ratings rely too much on beneficiary survey information to be used as an indicator of contract compliance because the results of the surveys may reflect factors other than a sponsor's non-compliance with program requirements (for example, high beneficiary complaints based on CMS-approved changes to plan benefit packages).

Response: In certain instances, beneficiary satisfaction is the most effective measure of an organization's contract performance. That effectiveness outweighs the risk of the measure's inaccuracy as a compliance measure presented by those rare instances when beneficiary dissatisfaction may result from factors outside the organization's control. Moreover, only a small portion of the Part C and D measures are focused on beneficiary satisfaction. In 2012, 5 of 36 total Part C measures, and 3 of 17 Part D measures, were based on beneficiaries' satisfaction with their plans. Therefore, low beneficiary satisfaction scores, while meaningful, will not by themselves cause an organization to receive a low summary plan rating.

Comment: Several commenters stated that plan ratings are an unreliable tool for measuring contract compliance because the stars are calculated based on relative performance among all Part C and D contracts. Therefore, every year, some sponsors will be rated below 3 stars regardless of the actual quality of their performance.

Response: The majority of plan rating measures are based on fixed 4-star thresholds, or 3-star thresholds for measures when an absolute regulatory standard has been established. For CY 2012, 28 of 36 Part C measures, and 9 of the 17 Part D measures, had fixed 3- or 4-star thresholds. Having a set threshold means that any entity meeting the established threshold will receive at least a 3 or 4 star rating for the measure. We determine the star cut points below 4-star (or 3-star) ratings in those measures with fixed thresholds as well as the entire range of ratings for the remaining measures through the use of statistical techniques that take into consideration the relative distribution of the data as well as the how the data clusters. For survey measures, significance testing is also used to determine the star ratings. Given the fixed thresholds for the majority of the measures, there is nothing in the Plan Ratings methodology that would prevent all sponsors achieving 4 or more stars on measures that have fixed 4-star thresholds or achieving 3 stars for measures when an absolute regulatory standard has been set. Additionally, while some of the cut points for the individual measures may be determined by examining the distribution of collected data, for the most part, those data sets are not normally distributed, where some number of contracts would have to be assigned 1- or 2-star ratings. Indeed, in any given year, it is possible for all Part C and D sponsors to achieve at least three-star summary ratings under the scoring methodology. Furthermore, a review of the summary plan ratings over the past 3 years would reveal that there are very few 1-star contracts and that a 3-star rating or better was achieved by a strong majority of contracts.

Comment: Several commenters stated that the annual plan ratings are a flawed mechanism for determining contract compliance because the measures used to calculate the ratings are based on data from different timeframes. That is, the measures do not provide a consistent ''snapshot'' of performance over a uniform evaluation period.

Response: We use the most recent data available to calculate the summary plan ratings each year, and a broad range of measures are necessary to provide a comprehensive picture of a sponsor's performance. In fact, the majority of plan ratings posted in October of a given year reflect findings from the most recent completed contract year (that is, there is a gap of only about 9 months between completion of a measure and the posting of the star rating). However, for some performance measures there is necessarily some greater lag time between data collection and analysis. The 3 consecutive year requirement should afford sponsors sufficient time to make operational changes that would be reflected in data used to calculate plan ratings by the end of the 3-year period.

We also note that in August 2010, the CMS Hearing Officer issued an opinion in favor of an organization that appealed CMS' denial of its contract qualification application based on a review of the organization's contract performance (including its plan ratings) during the 14 months preceding the application submission date. (In the Matter of United Healthcare Insurance Company, Docket No. 2011 C/D App 1–10.) Among its arguments, the organization asserted that CMS should not include plan ratings as a factor in assessing past contract performance because the ratings were based on conduct that occurred prior to the 14-month look-back period. The Hearing Officer addressed this argument in a footnote to the opinion where he stated that,

* * * in future similar circumstances * * * CMS could reasonably consider an organization out of compliance for failure to meet established performance metrics, even if a portion of the data used to evaluate compliance is technically derived from instances outside the 14 month window.

Comment: Several commenters stated that CMS should provide advanced notice of each year's plan rating measures so that plan sponsors can develop and implement operational policies that will allow the sponsor to successfully meet the performance standards of each measure. A commenter noted that CMS released the measures for the CY 2012 plan ratings in late 2011, just prior to posting the results of the CY 2012 ratings.

Response: We have already informed sponsors that we will release the plan rating measures at the start of each calendar year. For example, on December 20, 2011, CMS issued, through the Health Plan Management System (HPMS), a request to drug and health plan sponsors for comments on our proposed measures for the CY 2013 plan ratings. In the memorandum we stated that we expected to publish the final set of CY 2013 measures in April 2012 along with a discussion of proposed measures for the CY 2014 ratings.

Comment: A number of commenters noted that CMS should take into consideration the characteristics (for example, income, age, health) of each sponsor's enrollees when assessing performance. For example, CMS should develop measures specifically tailored to account for the unique populations served by SNP plans.

Response: We have frequently considered the adoption of modifying the plan rating standards to account for unique differences in the characteristics of certain plan membership profiles. However, we have not yet found any statistical support for the special treatment of certain plans under the plan rating methodology.

The 2011 Part C and D plan rating results, for example, provide no support for the argument that MA organizations offering SNPs face special challenges in achieving good star ratings. The plan rating results for all Part D contracts, when broken down into three categories by percentage of SNP enrollment per contract (SNP enrollment less than 50 percent, SNP enrollment greater than 50 percent, and SNP enrollment 100 percent of total contract enrollment) show that approximately 15 percent to 18 percent in each category receive less than 3 stars. The Part C results are slightly more mixed but still show that contracts with SNP enrollment receiving less than 3 stars are decidedly in the minority relative to their peers. Among the same enrollment percentage categories described for Part D, the percentage of Part C contracts with low star ratings ranged from approximately 15 percent to 29 percent. Interestingly, the rate of less than 3 star performers drops when SNP enrollment increases from 50 percent or more to exactly 100 percent. That is, contracts with only SNP members tend to have strong performance, equal to contracts with fewer than 50 percent SNP members.[1] Therefore, we can easily conclude based on these data that having SNP members in a contract does not pull down summary plan rating results for either the Part C or Part D ratings.

Comment: A few commenters noted that the regulation should exempt from termination those sponsors that are showing improvement but have not yet reached 3 stars in the third year.

Response: Such an interpretation is unworkable as sponsors could avoid termination for as long they can demonstrate improvement without meeting the 3-star standard.

Comment: A commenter stated that CMS should provide midyear reports to sponsors of their progress on plan ratings.

Response: The data collection for several of the measures are only once a year, so it is not possible to make midyear assessments of a sponsor's plan rating performance. Sponsors should consider the plan ratings CMS issues each year to be interim reports during the 3-year period preceding possible contract termination.

Comment: A commenter stated that CMS should release plan ratings before bids are due so that sponsors about to be terminated do not expend resources on preparation for upcoming plan year.

Response: We cannot adjust our plan rating analysis and publication schedule solely to accommodate sponsors with two consecutive years of low ratings. Those organizations should review their operations and make their own assessment of the likelihood of achieving a rating of at least 3 stars after the submission of a contract qualification application.

Comment: A few commenters supported this provision, but also expressed their concern that its application will reduce the availability of low premium plans which are often low-rated. The commenters also referenced a study by Avalere Health

[1] CMS conducted this analysis based on plan enrollment data available at *https://www.cms.gov/PrescriptionDrugCovGenIn/06_Performance Data.asp* and plan rating data available at *https://www.cms.gov/MCRAdvPartDEnrolData/*.

(released on October 19, 2011; *http://www.avalerehealth.net/wm/show.php?c=&id=890*) that found that 52 percent of the stand-alone PDPs eligible for LIS auto assignment and reassignment have a 2 or 2.5-star rating during 2012. None of those plans has a 5-star rating and 16 have a 4-star rating.

Response: We have analyzed the 2012 contracts rated below 3 stars and found no correlation between low rated plans and low premiums. However, to the extent that the Avalere study suggests that Part D plans to which LIS beneficiaries are assigned tend to achieve disproportionately lower ratings, we believe that the threat of termination provides the correct incentive to these plan sponsors. That is, we can force sponsors that might otherwise ignore their plan ratings, content to compete solely on price or operate in Medicare markets with little or no competition, to dedicate the resources and attention necessary to provide at least a satisfactory level of services to their members. For LIS plans in particular, this new authority makes it clear that focusing solely on bidding below the annual benchmark to keep LIS enrollment high is no longer a viable long-term Part D business strategy.

Comment: A commenter stated that CMS should add a measure based on how often the sponsor makes exceptions and appeals determinations in favor of the beneficiary.

Response: The plan ratings already include measures, based on sponsors' IRE results, of how often the IRE agrees with a sponsor's decision to deny a claim. We believe this measure is effective in achieving the same goal suggested by the comment; measuring the extent to which the plan sponsor is making correct decisions about its members' Part D drug coverage.

Comment: A commenter stated that CMS should assign dual-eligible beneficiaries only to plans rated at more than 3 stars.

Response: This comment concerns CMS' process for automatically assigning and reassigning dual-eligible beneficiaries to stand-alone PDPs with premiums set at or below the regional benchmark. It does not concern the use of the establishment of the plan ratings as a contract requirement or as a basis for contract termination and therefore is outside the scope of the proposed regulatory change.

Comment: A commenter stated that CMS should provide information on how it monitors 4Rx data and LIS status for beneficiaries.

Response: We have provided and will continue to provide this information to sponsors through the Health Plan Management System (HPMS) related to our monitoring of 4Rx data and LIS status accuracy.

Comment: A commenter stated that it supports the inclusion of measures related to enrollment, LIS, and MTM.

Response: This comment is a recommendation for the inclusion of certain measures in the Part D plan rating methodology. As it does not have a bearing on the use of the current plan ratings as administrative and management requirements under the Part C and D programs or as a basis for contract termination, the comment is outside the scope of the proposed regulatory change.

After consideration of the public comments received, we are finalizing the policy without modification.

3. Denial of Applications Submitted by Part C and D Sponsors With a Past Contract Termination or CMS-Initiated Non-Renewal (§ 422.502 and § 423.503)

In accordance with § 422.502(b) and § 423.503(b), applicants with current or prior contracts with CMS are subject to denial of their applications if they fail to comply with the requirements of the Part C or D programs during the preceding 14 months, even if the applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the April 2011 final rule (76 FR 21432), we added provisions at § 422.502(b)(2) and § 423.503(b)(2) concerning the treatment of entities submitting applications to us when the entity has operated its contract(s) with CMS for less than 14 months at the time it submits a new application or service area expansion request. In the interest of ensuring that new entrants to the Part C or Part D programs can fully manage their current contracts and books of business before further expanding, we added a provision that in the absence of 14 months' performance history, we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D program, respectively.

We proposed to further refine our approach to using past performance in making application determinations. Specifically, we are concerned about entities submitting applications to us when the entity has had a previous Medicare contract terminated or non-renewed by CMS. We initiate termination or non-renewal of a contract only when the MA organization or Part D sponsor has committed extremely serious violations of the Part C or Part D program. In the past, these contract actions by CMS have been rare. The bases for a termination are specified in § 422.510 and § 423.509, and include such serious violations as substantially failing to carry out the terms of its Medicare contract; committing fraud; and failing to carry out the requirements for beneficiary access to services by, for instance, not implementing required appeals and grievance processes or not establishing provider and pharmacy networks that meet our requirements. The bases for a CMS-initiated non-renewal are specified in § 422.506(b) and § 423.507(b), and include the same list of violations, plus several others. Nevertheless, despite the seriousness of termination and CMS-initiated non-renewal actions, and the underlying noncompliance that would have led to such a drastic step, the regulation is silent concerning when these organizations may re-enter the Part C and Part D programs. As such, we currently rely upon the past performance provisions in § 422.502(b)(1) and § 423.503(b)(2) to determine whether an application from a previously terminated or CMS-non-renewed organization is approvable. These provisions limit the period of time we can review for purposes of assessing past performance to 14 months. Fourteen months is a reasonable amount of time to review the performance of organizations with current and ongoing Medicare Part C and Part D contracts. In the case of organizations whose performance was so poor as to have their contract(s) terminated or non-renewed by CMS, we believe that a 14-month look-back is an inadequate amount of time.

In contrast to the regulation's silence on a ''waiting period'' for organizations whose contracts have been terminated or non-renewed by CMS, long-standing provisions at § 422.506(a)(4), § 422.508(c), § 422.512(e), § 423.507(a)(3), § 423.508(e), and § 423.510(e) require that organizations that have voluntarily non-renewed or terminated their contracts must wait 2 years before they may reenter the program. We believe that the interval between the effective date of a contract's CMS-initiated termination or non-renewal should be no less than in the case of a voluntary termination or non-renewal. Indeed, a period of greater than 2 years is appropriate, for these entities have broken faith with the program in a more significant way than in the case of a voluntary non-renewal.

As such, we proposed to modify the past performance review period to capture CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application. The selection of 38 months accounts for a 3-year period, plus the 2 months of the year during which applications are being prepared for submission to CMS. Three years represents 1 additional year compared to the 2 years of waiting time for voluntary non-renewals. To make this change, we proposed adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) to state that if CMS has terminated or non-renewed an MA organization's or Part D sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, we may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C or Part D program even if the applicant currently meets all of the requirements of this part.

Additionally, in the April 2011 final rule, we defined ''covered persons'' for the purpose of determining which organizations are prohibited from re-contracting with CMS for the two years following a voluntary non-renewal. Specifically, we codified that the 2-year ban on new Part C or Part D sponsor contracts to which non-renewing organizations are subject under the regulation be expanded to include organizations owned or managed by an individual (referred to as a covered person) who served in a similar capacity for a previously non-renewed Part C or Part D organization. The requirement assists us in prohibiting and preventing each such organization from manipulating the Medicare program by reapplying for a contract as a new organization during the 2-year ban, when the applying organization has common ownership and management control with the previous non-renewing organization. In essence, this requirement helps ensure that the provisions of the 2-year application prohibition are given full effect.

For consistency and to prevent the same sort of manipulation by organizations whose contracts have been terminated or non-renewed by CMS, we proposed to add new paragraphs at § 422.502(b)(4) and at § 423.503(b)(4) to replicate the existing language concerning covered persons as currently exists for voluntarily non-renewing organizations. Specifically, the newly proposed language states that in implementing the 38-month provision, we may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. As with the voluntary non-renewal provisions, in this instance ''covered person'' would mean one of the following: (1) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent; (2) an owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; (3) a member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

The combined effect of these proposals is to ensure appropriate requirements exist concerning program re-entry subsequent to all types of terminations and non-renewals, and to strengthen the past performance review to capture the most serious types of non-compliance (resulting in CMS-initiated terminations and non-renewals) for a more reasonable period of time.

Comment: Some commenters recommended that CMS delete the proposed language authorizing CMS to deny applications from entities whose covered persons had also served as covered persons for a contract terminated or non-renewed in the prior 3 years. Commenters stated that the provision is overly broad and may unfairly cover individuals who, for example, join the board shortly before CMS terminates or nonrenews a contract.

Response: We appreciate commenters' concerns. However, it is incumbent on prospective directors and shareholders to conduct proper due diligence concerning a sponsor's Part C and D compliance history prior to accepting a board appointment or purchasing a substantial number of shares of stock. Also, as discussed in the preamble to the proposed rule, the ''covered person'' definition was adopted previously under the two-year ban that follows a contract's voluntary non-renewal. It is important to apply the same standard to CMS-initiated terminations and non-renewals in order to maintain consistency and prevent entities from manipulating the Part C and D contract application process.

Comment: Many commenters expressed general support for the proposed language, including the language related to ''covered persons''. However, several expressed concern that the 3-year look back period is too short. They suggested a 10-year look back period instead.

Response: We appreciate the commenters' support. However, we believe that extending the look back period to 10 years would be unduly punitive, as that would effectively exclude a terminated or non-renewed sponsor from the Part C or D programs for 10 years. Our intent in adopting this provision was in part to remedy the disparity in consequences between sponsor-initiated non-renewals and CMS-initiated terminations or non-renewals. As discussed in the proposed rule, we believe that the 3-year ban on Part C or D program participation created by the 38-month past performance look-back period meets that goal by imposing some administrative penalty where none existed for operating a Medicare contract so poorly. It also makes certain that the penalty was greater than that associated with voluntary non-renewal. Three years is also a reasonable period of time during which a terminated or non-renewed sponsor could make improvements to its organization in preparation for providing quality services should it elect to re-enter the Part C and D markets. We believe that a 10-year exclusion period goes well beyond what is necessary to achieve our policy goals and could be viewed as excessively harsh by health and drug plan sponsors and the communities they serve.

Comment: Several commenters remarked that the 14-month look back period for past performance analysis was too short.

Response: The 14-month look back period for the past performance analysis of all Part C and D contract applicants was established through previous rulemaking. As the regulatory change described here concerns a modification to the length of the look back period only for applicants with previous CMS-terminated contracts, comments concerning all other types of applicants are outside the scope of the proposed rule.

Comment: A few commenters expressed concern that entities would attempt to get around the 3-year look back period for contracts terminated or non-renewed by CMS by voluntarily non-renewing their contracts before CMS terminates them.

Response: We appreciate commenters' concerns. We will be mindful of organizations attempting to avoid the consequences of the new provision by voluntarily non-renewing. However, we believe that this type of manipulation is unlikely because voluntary non-renewal already carries with it a 2-year ban.

After consideration of the public comments received, we are finalizing these provisions as proposed.

D. Improving Program Efficiencies

We believe that finalizing the regulations discussed in this section will reduce regulatory burdens for MA organizations, Part D sponsors, and cost contractors; lower transaction costs; and reduce waste and unnecessary spending—all of which will, in turn, help keep costs down and improve the quality of care received by Medicare beneficiaries. Non-renewing cost contractors will also save money because we are finalizing a rule that eliminates the regulatory requirement to purchase print advertising announcing their non-renewals. We are also finalizing more flexible rules regarding agent/broker compensation, which means MA organizations and Part D sponsors will no longer be tied to historic agent/broker compensation amounts and may save transaction and other costs. Finalized regulations that enable daily cost-sharing of prescription drugs will not only save money for the Part D Program and those beneficiaries who discover during their initial fills that certain drugs do not work for them, but will also result in fewer unwanted drugs that create problems of disposal or safekeeping.

The finalized proposals mentioned previously and others are outlined in Table 5.

TABLE 5—PROVISIONS TO IMPROVE PROGRAM EFFICIENCIES

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.D.1	Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal.	Subpart L	417.492	N/A	N/A	N/A	N/A
II.D.2	New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D–SNPs).	N/A	N/A	Subpart C	422.102	N/A	N/A
II.D.4	Clarifying Coverage of Durable Medical Equipment.	N/A	N/A	Subpart C	422.100 422.111	N/A	N/A
II.D.5	Broker and Agent Requirements	N/A	N/A	Subpart V	422.2274	Subpart V	423.2274
II.D.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	N/A	N/A	N/A	N/A	Subpart D	423.100 423.104 423.153

1. Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal (§ 417.492)

Section 1876 of the Act provides the Secretary with the authority to enter into contracts with HMOs on a cost basis. While section 1876(k)(1)(A) of the Act precludes the Secretary from entering into new cost contracts after the establishment of Part C, existing contracts are grandfathered, and subject to regulations, including § 417.492, which sets forth rules that apply to non-renewal of a cost contract.

In the event that such a contract is non-renewed, the cost plan or CMS must notify both the enrollees of the organization and the general public of the non-renewal. As specified in current § 417.492(a)(1)(iii), public notification must include ''notice in one or more newspapers of general circulation in each community or county located in the HMO's or CMP's geographic area.'' We proposed removing the current requirements at § 417.492(a)(1)(iii) and (b)(1)(iii) for non-renewing cost-contracting plans (in voluntary non-renewal situations) and for CMS (in CMS-initiated non-renewal situations) to notify the general public concerning the impending non-renewal. Our proposed removal of this requirement was motivated by the cost of newspaper advertisements and the declining rate of newspaper circulation. In addition, we believe that the requirement that cost plans provide personalized non-renewal information is sufficient to ensure adequate non-renewal notice.

Comment: A commenter wrote that waiving the requirement for printing a public non-renewal notice would have virtually no cost savings to a plan.

Response: Although we do believe there will be some savings associated with not having to print a public notice, we also believe that the provision will reduce unnecessary burden on plans.

Comment: A commenter stated that retaining the public notification requirement could help ensure that beneficiaries have more knowledge about plan changes.

Response: Because plans are still required to contact each enrollee when non-renewing a plan for the upcoming year, we believe that beneficiaries will continue to have sufficient notification.

After consideration of the public comments received, we are finalizing the policy without modification.

2. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D–SNPs) (§ 422.102)

Section 2602(c) of the Affordable Care Act charged us with making Medicare and Medicaid work together more effectively to improve patient care and lower costs. In our October 11, 2011 proposed rule (76 FR 63018), we proposed to give certain SNPs additional flexibility with respect to plan design as a means of furthering this goal of better integrating care for dual eligible beneficiaries.

Section 1852(a)(3) of the Act and our regulations at § 422.2, § 422.100(c)(1), and § 422.102 allow us considerable discretion in deciding what benefits beyond those covered under Medicare Parts A, B, or D can be offered to MA enrollees as a ''mandatory supplemental benefit'' that is included in an MA plan for every enrollee who joins the plan, as opposed to optional supplemental benefits which are offered to all enrollees, but for which coverage is only provided to enrollees who choose to pay for the optional benefit. In our October 11, 2011 proposed rule, we proposed providing certain fully integrated dual eligible SNPs (FIDE–SNPs) with the flexibility to offer additional supplemental benefits because we are interested in assessing whether certain supplemental benefits could help prevent health status decline in the dual eligible population and reduce the quantity and cost of future health care needs. In order to implement this proposal, we proposed amending § 422.102 to add a new paragraph (e) specifying that, subject to our approval, and as specified annually by us, certain fully integrated dual eligible SNPs (FIDE SNPs) may offer additional supplemental benefits beyond those other MA plans may offer, where CMS finds that the offering of such benefits could better integrate care provided under Medicare and Medicaid for the dual eligible population. All such benefits would also have to otherwise be consistent with the rules for supplemental benefits under Part 422, including § 422.2, § 422.100(c)(1), and § 422.102.

We proposed limiting the new supplemental benefits flexibility offered under this provision to FIDE SNPs defined at § 422.2 that are currently operational, operated in the previous contract year, and meet certain CMS criteria including, but not limited to, being of high quality (as defined by CMS in future guidance). We believed that this approach would be most consistent with the objective of keeping beneficiaries at risk of institutionalization in their homes and preventing health status decline that results in additional utilization of health services, and lowering costs for the Medicaid and Medicare programs. We also proposed to further limit the additional benefit flexibility under the proposed rule to those qualified SNPs that serve only full-benefit dual eligible beneficiaries. We requested comment on whether extending supplemental benefit flexibilities under our proposed § 422.102(e) to eligible SNPs that are SNP types other than FIDE SNPs could measurably reduce unnecessary utilization and improve beneficiary outcomes in an equivalent manner.

In our proposed rule, we also requested comment on what specific categories and types of supplemental benefits we should consider for the purposes of extending benefit flexibility to qualified FIDE SNPs that would be participating in this initiative, as well as on the circumstances under which plans should be permitted to offer these additional supplemental benefits. We also requested comment on additional restrictions that should govern plans' ability to offer these additional benefits, and how we might be able to expand the scope of approved supplemental benefits in a manner that allows plans to serve their dual eligible enrollees effectively and efficiently. We additionally requested comment on ways to minimize this proposed provision's cost impact on dual eligible beneficiaries, while ensuring that States, SNPs, and providers can feasibly provide additional supplemental benefits to a dual eligible population.

No commenters opposed our overall policy proposal to offer new supplemental benefits flexibility to certain SNPs. We also received no comments on our planned approach to further implement this policy through guidance in our final Annual Call Letter and in Chapter 4 of the *Medicare Managed Care Manual.*

Comment: In our proposed rule, we requested comment on whether the benefit flexibility under this provision should be limited to FIDE SNPs, as defined at 42 CFR 422.2, or whether we should extend it to other SNP types. Most of the comments that we received on this issue recommended that we extend this flexibility to all SNP types so that SNPs could target additional supplemental benefits to special needs individuals enrolled in chronic SNPs (C–SNPs) and institutional SNPs (I–SNPs). Some commenters recommended that we extend this benefit flexibility to all dual eligible SNPs (D–SNPs) so that a larger number of dual eligible beneficiaries, including those dual eligible beneficiaries residing in geographic areas without an operational FIDE SNP, could access additional supplemental benefit offerings. A few commenters supported our proposal to limit this new supplemental benefit flexibility to FIDE SNPs only, because they believed that FIDE SNPs were best positioned to deliver integrated services that prevent enrollee institutionalization.

Response: After considering the comments we received, we are finalizing our proposed provision with modification to allow new supplemental benefit flexibility for certain D–SNPs that meet a high standard of integration and minimum performance and quality based standards, where CMS finds that the offering of such benefits would better integrate care for the dual eligible population. We outline these integration, contract design, performance, and quality-based criteria for a D–SNP that would meet this standard in the final CY 2013 Annual Call Letter. We plan to update these criteria annually, as necessary. We believe that expanding the new supplemental benefit flexibility to a larger pool of D–SNPs that meet certain standards in accordance with State policies is consistent with our goal of better integrating care for dual-eligible beneficiaries. By expanding this supplemental benefit flexibility beyond FIDE SNPs, more dual eligible beneficiaries will have access to additional supplemental benefits that are designed to bridge the gap between Medicare and Medicaid services. By limiting this flexibility to qualified D–SNPs—all of which must contract with the State starting in 2013—rather than allowing the flexibility for all SNP types, we can better ensure that plans will use this benefits flexibility to increase integration and care coordination.

Furthermore, we believe that, because D–SNPs must adhere to the State contract requirements at § 422.107, limiting this new benefit flexibility to D–SNPs rather than extending it to all SNP types (C–SNPs and I–SNPs) would not provide an incentive to MA organizations to create SNPs for the purposes of qualifying for this new benefit flexibility. Therefore, we are finalizing our proposed rule with modification to afford all D–SNP types that meet a high standard of integration and meet minimum performance and quality-based standards the opportunity to qualify for this new supplemental benefit flexibility, even if they are not FIDE SNPs. We are modifying our regulations at § 422.102 to add a new paragraph (e) specifying that, subject to CMS approval, D–SNPs that meet a high standard of integration and minimum performance and quality-based standards may offer additional supplemental benefits beyond those other MA plans may offer where CMS finds that the offering of such benefits would better integrate care for the dual eligible population.

Comment: The majority of comments we received on our supplemental benefit flexibility proposal related to the types and categories of supplemental benefits that plans would be permitted to offer under this flexibility. A large number of commenters requested that we include adult day care services as a category of supplemental benefits that plans would be permitted to offer under this new supplemental benefit flexibility. The commenters noted that adult day care services are not covered by either Medicare or Medicaid in most states. They further noted that many plans that have experienced reduced utilization of long-term care services attribute this reduction to their enrollees' use of adult day care services. Other commenters suggested that we include assistive devices, nutritional supplements, incontinence supplies, and primary and secondary prevention services as permissible types of supplementary benefits under this provision.

Response: We appreciate the commenters' suggestions. We believe that the additional supplemental benefits that will be available under this provision may be appropriate to the extent that they assist Medicare-Medicaid beneficiaries with activities of daily living, (ADLs), (for example, eating, drinking, dressing, bathing, grooming, toileting, transferring, and mobility) and/or instrumental activities of daily living, (IADLs), (for example, managing a home, transportation, grocery shopping, preparing food, financial management, and medication management). Additionally, we believe that the additional supplemental benefits afforded under this provision should be those benefits that bridge the gap between Medicare and Medicaid services and that have the potential to decrease unnecessary utilization of health care services by the dual eligible population. We have considered comments that we received in response to our proposed rule according to the standard we describe previously. We outline supplemental benefit categories that plans may offer under this provision, as well as guidance on the scope of these additional supplemental benefits, in our final CY 2013 Annual Call Letter. We also note that we will provide qualified D–SNPs with operational guidance on the bid submission process in future guidance.

Comment: In the proposed rule, CMS requested comment on whether it should limit this benefit flexibility to D–SNPs that only enroll dual eligible beneficiaries with full Medicaid benefits. A few commenters supported the limitation to full-benefit dual eligibles, noting that these individuals would receive the most benefit from additional supplemental benefits that are designed to enhance Medicare and Medicaid service integration. A significant number of commenters felt that limiting the additional supplemental benefit flexibility to full-benefit dual eligibles was needlessly restrictive, and would not allow plans to offer supplemental benefits designed to prevent partial dual eligibles (that is, dual eligible beneficiaries that do not qualify for full Medicaid benefits) from declining to full-benefit status.

Response: We agree with commenters' statements that the additional supplemental benefits that we will allow D–SNPs to offer under this provision could help prevent partial dual eligible beneficiaries from spending down to full dual status. We also recognize the potential value of supplemental benefits for dual eligibles that cycle in and out of full Medicaid eligibility during the year. We believe that allowing plans to offer additional supplemental benefits to partial duals would further our goal of aligning Medicare and Medicaid benefits to prevent health status decline and prevent unnecessary utilization of acute and long term care services. Consequently, as noted previously, we are permitting certain, D–SNPs to offer additional supplemental benefits even if they are not FIDE SNPs.

Comment: In our proposed rule, we requested comment on how our proposal would impact costs for dual eligible beneficiaries. All commenters that commented on this issue recommended that we require SNPs that offer new supplemental benefits under this provision to provide these benefits to dual eligible enrollees at zero cost-sharing and with no increase in premium. Many commenters also recommended that we prohibit plans from creating new supplemental benefits offerings that duplicate Medicaid services because plans that offer supplemental benefits that are identical to Medicaid benefits could modify their supplemental benefits in a manner that would leave enrollees liable for higher cost-sharing. These commenters suggested that CMS require SNPs to describe how the new Medicare supplemental benefits and existing Medicaid benefits will differ and work together, as a condition of participating in this new benefit flexibility initiative.

Response: We share commenters' concerns that duplication of Medicaid benefits in plans' supplemental benefit offerings has the potential to put dual eligible beneficiaries at risk for higher cost-sharing. We do not intend for the new supplemental benefits offered under this provision to duplicate or supplant Medicaid benefits. In response to such concerns and comments received on the draft CY 2013 Call Letter, our final CY 2013 Call Letter requires qualifying D–SNPs, to attest, at the time of bid submission, that the additional supplemental benefit(s) that the SNP describes in its plan benefit package (PBP) do not inappropriately duplicate an existing service(s) that enrollees are eligible to receive under a waiver, the State Medicaid plan, Medicare Part A or B, or through the local jurisdiction in which they reside. Additionally, in order to evaluate how D–SNPs are implementing this new benefit flexibility, we indicate that we will require D–SNPs that participate in this new benefit flexibility initiative to submit a mandatory quality improvement project (QIP) under § 422.152(a)(2) on measures related to the goals of this initiative, as determined by CMS. Finally, in response to the previous comments urging that benefits offered under the new benefit flexibility be made available without cost sharing or additional premium charges, we have added language to § 422.102(e) requiring that benefits be offered to the beneficiary at no additional cost (that is, zero-cost sharing and with no attributable premium increase).

Comment: Several commenters recommended that CMS establish a means of assessing whether the new supplemental benefits offered under this provision lower costs, reduce unnecessary utilization, and improve integration of Medicare and Medicaid services.

Response: We agree with commenters' recommendations. CMS will develop a means for evaluating the effectiveness of this new supplemental benefit flexibility and will detail our evaluative methodology in future guidance. We will also provide qualified D–SNPs with operational guidance at that time.

Comment: A commenter requested clarification on the years that SNPs must have a State contract in order to qualify under the definition of ''currently operational,'' as discussed in the CY 2012 Annual Call Letter and the preamble to our proposed rule. Another commenter suggested that we revise our requirement that SNPs must have operated in the previous contract year, in order to allow new SNPs to qualify for this new supplemental benefit flexibility.

Response: We reject the commenter's suggestion that SNPs that have not operated in the previous contract year should qualify for this new supplemental benefit flexibility. We are maintaining our requirement that D–SNPs must have operated in CY 2012 and be operating in CY 2013 in order to qualify to participate in this supplemental benefit flexibility initiative because, without a record of operation in the prior contract year, CMS would be unable to determine whether a D–SNP would meet the minimum eligibility requirements (that is, contract design, integration, performance, and quality-based requirements) for this new benefit flexibility. We are updating our regulations at § 422.102(e) to reflect the prior year operation requirement. Furthermore, we believe that D–SNPs that have not operated for at least one year would lack the experience necessary to identify supplemental benefits that would effectively serve the specific needs of their dual eligible enrollees. D–SNPs must have a State contract in order to qualify to participate in this initiative. In our final 2013 Annual Call Letter, we clarify additional operational and contract design requirements for D–SNPs participating in this benefits flexibility initiative. Unless otherwise stated, these contract design requirements apply to the specific SNP plan (that is, SNP plan benefit package), and not the larger MA contract.

Based on our review of the public comments, we have modified our proposal as discussed in the previous responses and we have also modified § 422.102(e).

3. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

In the October 11, 2011 proposed rule (76 FR 63049 and 63050), we proposed to require by regulation that MA organizations provide in their contracts with hospitals that they will reduce payments for Part A hospital services for serious events that could be prevented through evidence-based guidelines, in accordance with the hospital-acquired conditions (HACs) and present on admission indicator (POA) policy that is currently required for hospitals paid under the Original Medicare Acute Care Hospital Inpatient Prospective Payment System (IPPS). We believed this proposed change was appropriate in order to bring MA requirements in line with current HAC–POA policy in the original Medicare program, as well as—in the near future—to the Medicaid program.

The HAC–POA policy aims to reduce medical errors, improve quality of care for beneficiaries, and reduce Medicare expenditures for poor quality care. We proposed to specifically apply the HAC–POA policy in the MA program by requiring MA organizations to include appropriate payment provisions in their contracts with hospital providers. We believed this would be consistent with the agency goal to further align the MA and original Medicare programs and the ACA requirements to expand the HAC–POA policy further to Medicaid and Medicare and to continue development of value-based purchasing programs.

We proposed to amend § 422.504(i)(3) by adding a new paragraph (iv) to require that, beginning in CY 2013, MA organizations provide in their contracts with hospitals that payment will not be made to contracting hospitals in the case of serious preventable events and hospital-acquired conditions in accordance with section 1886(d)(4)(D) of the Act and all applicable Medicare policies. We solicited comments and recommendations on what other issues to consider in finalizing our proposal to require a payment reduction where payment would be reduced under the current IPPS HAC–POA policy to MA plans.

Comment: We received 17 comments on the proposal. All commenters expressed support for the goals of the policy, that is, to ensure quality within hospitals and reduce costs for unnecessary or poor care. However, reactions were mixed to the proposal to implement this goal through the contracting process.

Several commenters representing beneficiaries and health care professionals expressed support for the proposal and encouraged CMS to continue efforts to more closely align the MA program with original Medicare and other public program initiatives consistent with the National Quality Strategy. A commenter discussed specific HAC conditions and requested that CMS remove healthcare-associated infections from the existing HAC policy.

Several commenters representing the MA industry supported the proposal, stating that implementation would not be burdensome and expressed their belief that their organization's existing contract provisions would be sufficient to implement the policy for CY 2013 as proposed. A commenter requested affirmation of the sufficiency of their plan's specific contract language. A commenter also recommended that the HAC–POA payment adjustment should also apply to non-contract hospital providers.

Response: We thank all commenters for expressing their support and their concerns and raising important questions for CMS to consider. We agree with commenters that reducing costs, while striving for high-quality healthcare for seniors is an important goal of this agency and for the DHHS. We appreciate the encouragement for CMS to continue efforts to more closely align the MA program with original Medicare and other public program initiatives consistent with the National Quality Strategy. We also recognize that, while many plans may already have payment systems or contract provisions in place that would accommodate immediate application of this policy, other payment models, and contractual structures may not, and would have to be amended to implement a reduction in payment for occurrences of HAC.

With regard to the comment requesting that CMS remove healthcare-associated infections from the existing HAC policy, we note that this comment is not within the scope of this rule. Specific HAC conditions are considered through public comment annually in the IPPS rule.

With regard to the comment that the HAC–POA policy should also apply to non-contract providers, we indicated in the October 11, 2011 proposed rule (76 FR 63049 and 63050), that the payment reduction is already required for payments to non-contract providers. MA plans must pay non-contract acute care hospital claims the same rate that they would be paid under the IPPS, and this includes adjustments for HACs and any other IPPS payment adjustments. This is specified in the MA Payment Guide for Out-of-Network Payments, available at: *https://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/oon-payments.pdf.*

Comment: Some commenters supported application of the policy with extra time allowed to understand requirements, modify contracts, redesign payment approaches, and incorporate POA reporting into claims processing systems. Several commenters requested that CMS set the deadline for implementation at January 1, 2014.

Response: We appreciate the support for the policy and fully recognize concerns about the additional time that would be needed in order to implement the policy. However, we are also cognizant of concerns expressed by other commenters regarding the operational implications of the policy, given, for example, the varied payment structures in place, and the need to modify and execute new contracts. We will need to fully understand such implications before we are able to establish a reasonable timeframe for implementing the policy. Therefore, at this time, we will not finalize the policy as proposed with a definitive implementation date. Instead, we intend to further study the implications of extending the HAC–POA policy to the MA program and, potentially, consider other ways to achieve the goals of the policy.

Comment: Several commenters were concerned about their ability to reasonably apply these requirements to non-DRG or fee schedule-based payment approaches, such as capitated, per diem or percentage-based models. They were concerned about the burden of "dissecting" every claim in order to calculate a payment and were concerned that every claim payment would be subject to negotiation with hospitals. Similarly, a commenter urged CMS to allow MA organizations flexibility to implement the policy in a way that would not require significant additional resources.

A commenter stated that MA organizations should not have to negotiate with hospitals on methodology, (that is, the methodology should instead be industry standard). Another commenter requested clarification that this policy would only apply to acute care inpatient hospitals. A few commenters expressed concerns with ensuring hospital compliance with reporting of serious adverse events and HACs.

Some commenters requested that plans with capitated payment models be exempt, stating that, under the capitated payment structure, the risk has already been placed on providers to reduce costly medical errors. A commenter stated that this proposal would stifle innovation of creative payment arrangements that the private healthcare industry uses to promote quality and efficiency and could result in increased costs for beneficiaries. A few commenters claimed to have specific recommendations for applying the HAC–POA policy goals to these types of payment structures, but did not provide them in their comments.

Response: We appreciate the thorough responses from commenters. As we indicated in the proposed rule, we recognize that there may be operational challenges to implementing the HAC–POA policy under varied payment models, which is why we requested specific suggestions and ideas to consider in order to find the best approach within the MA program to reduce the occurrence of HAC conditions and encourage efforts by hospitals to increase quality of care. We believe that exempting some MA organizations based on their existing payment structures with hospitals would result in inconsistent application of the policy and, consequently, failure to advance the goal of reducing these preventable medical errors. However, we do recognize the operational concerns expressed by the commenters. Therefore, we believe that the most prudent approach at this time is to continue to study the implications of extending the HAC–POA policy to the MA program in order to determine how best to incorporate the HAC–POA policy and other quality initiatives into the MA program.

Comment: With respect to the proposal to add this policy as a contractual requirement through § 422.504(i)(3), a commenter requested greater transparency and full disclosure to the public with respect to the types of contractual flexibility that CMS would allow. Other commenters were concerned about CMS over-regulating MA contracts, setting precedent for regulating MA financial arrangements and the burden of contract negotiations. Several commenters stated that hospital contracting is a multi-year process and that opening the contract for one provision would subject the entire contract to renegotiation, potentially resulting in increased costs to MA organizations, enrollees, and CMS. A commenter was concerned that smaller MA organizations might be disadvantaged in negotiating this payment reduction with hospitals.

A few commenters recommended that we revise the proposed rule to effectuate the policy goals through NCDs or other coverage requirements, rather than contracting/payment provisions. They argued that this would allow MA organizations to implement in a manner that is most appropriate to their provider networks without requiring MA organizations to make changes to their existing contracts, (for example through manual provisions). A commenter requested a model notice for MA plans to issue to hospitals describing the revised coverage policy for HACs and POA indicator reporting.

Several other commenters requested that CMS withdraw the proposal and engage in a collaborative effort with MA organizations to develop alternative approaches to achieve the policy goal of reducing HACs and securing higher-quality hospital care for beneficiaries in the MA program.

Response: We thank commenters who offered alternative solutions and we appreciate the comments expressing concern about opening up potentially lengthy and costly contract negotiations. We also understand, based on comments received, that some MA organizations may already have sufficient contract provisions in place to implement the policy without further negotiations. However, we agree with commenters that the proposal requires further consideration and discussion. Therefore, after consideration of the public comments received, we are not finalizing the proposed policy at this time. However, we will continue to explore alternative approaches to achieve a reduction in HACs, reduce costs for unnecessary medical care and ensure high-quality hospital care for beneficiaries in the MA program.

4. Clarifying Coverage of Durable Medical Equipment (§ 422.100 and § 422.111)

MA organizations and other stakeholders have asked for our guidance on whether MA organizations can limit enrollees to specified durable medical equipment (DME) manufacturers and brands. Some MA organizations have also asked us whether they could offer lower cost-sharing for ''preferred'' DME products or brands versus ''non-preferred'' DME products or brands. In section 50.1 of Chapter 4 of the Medicare Managed Care Manual, ''Benefits and Beneficiary Protections'' (see *http://www.cms.gov/manuals/downloads/mc86c04.pdf*), we specified that, beginning in CY 2011, plans could establish several cost-sharing levels (that is, tiers) for DME items, supplies, and Part B drugs, provided that: (1) The highest cost-sharing tier is at or below the relevant cost-sharing threshold established by CMS for DME and Part B drugs; and (2) plans ensure access to all products through the established network of providers. However, we have not specified in regulation or guidance whether network-based MA plans may, within a specified category of DME, limit coverage to the DME brands, items and supplies of specific (preferred) manufacturers.

Since we understand that some MA organizations are currently limiting DME coverage to certain brands and manufacturers, we believe it is important to establish a regulatory framework for the protection of beneficiaries by ensuring appropriate and adequate MA enrollee access to DME brands, items, and supplies. Additionally, we believe that MA plans working with MA clinicians are positioned to increase MA program efficiencies by allowing plans to negotiate bulk discounts for high-quality items.

Accordingly, under our authority in section 1856(b)(1) of the Act, to establish MA standards by regulation, and in section 1857(e) of the Act, to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed the requirements discussed later in this final rule with comment period, followed by a discussion of any applicable comments we received on the proposal.

We received 43 comments in response to our proposed requirements. Commenters included MA organizations and other industry representatives, beneficiary advocacy groups, DME manufacturers and representatives of DME manufacturers, and certain pharmacy groups. The majority of the comments focused on our proposed beneficiary protections. We have provided a brief summary of each of the proposed beneficiary protections to be required of MA plans that elect to limit provision of DME to specific brands and manufacturers. Each proposed beneficiary protection is followed by a discussion of applicable comments on that proposal, if any. Subsequent to this discussion, we address several additional comments associated with more general issues related to the proposed rule.

a. Access to Preferred DME Items and Supplies

We proposed requiring that MA organizations wishing to limit coverage within a specific category of DME to specific brands, items and supplies of ''preferred'' manufacturers take necessary steps to ensure that enrollees have access to all preferred manufacturer items and brands through their contracts with their network of DME suppliers. We reflected this change in proposed § 422.100(l)(2)(i). We received no comments on this proposal.

b. Medical Necessity Requirements for DME Items and Supplies

In accordance with § 422.112(a)(6)(ii) of the MA program regulations, MA organizations must have established policies and procedures that allow for individual medical necessity determinations if there is a question about whether a service or item, considered medically necessary by an enrollee's provider, should be covered. MA organizations making medical necessity determinations must have a medical director, who is a physician, ensuring the accuracy of organization determinations and reconsiderations as per § 422.562(a)(4). Therefore, we proposed requiring MA organizations—to the extent that they elect to limit coverage of DME brands, items and supplies to preferred manufacturers—to provide coverage of any DME brands, items and supply deemed medically necessary, including DME brands, items, and supplies made by non-preferred manufacturers. We reflected this change in proposed § 422.100(l)(2)(ii).

Comment: Several commenters were concerned about the burden of the medical necessity process for enrollees and their providers. A commenter pointed to our mention of § 422.112(a)(6)(ii) and § 422.562(a)(4) which requires MA organizations to have a medical director and established policies and procedures that allow for individual medical necessity determinations at the MA organizational level. These citations suggested that a formal petition from the plan is required for medical necessity. Several commenters explicitly asked that the enrollee's provider have the right to determine medical necessity. Several commenters requested clarification on the specific process for a medical-necessity determination; for example, whether the enrollee petitions the plan for a non-preferred brand and, if so, within what timeframe response can be expected.

Response: We wish to clarify that the medical necessity process concerning brand/manufacturer of DME items is the same as that for any health care service offered by a plan. As we stated in the proposed rule, we are not adding an exceptions process for DME similar to the Part D formulary exceptions process. While medical necessity requests are the same for DME as any other health care service offered by a plan (that is, they must follow the requirements for medical necessity at § 422.112(a)(6)(ii), § 422.562(a)(4) and, more generally, the requirements for organizational determinations at § 422.566), we do want to clarify that medical-necessity status may be initiated by the enrollee's provider if the provider believes that a particular brand of DME is medically necessary. Our purpose in citing § 422.112(a)(6)(ii) and § 422.562(a)(4) was to clarify that plans are not unconditionally bound by an enrollee provider's medical-necessity declaration. That is, plans have the right to deny medical-necessity requests made by the enrollee's provider. However, the enrollee has the right to an appeal or expedited appeal if the plan denies the provider's medical-necessity determination. We are also reinforcing that, as specified in § 422.112(a)(6)(i), requests for medically-necessary items must be responded to in a timely fashion.

c. Transition Period for Coverage of Non-Preferred DME Items and Supplies

As provided under § 423.120(b)(3), MA organizations offering an MA–PD plan and Part D sponsors are required to provide for an appropriate process for enrollees transitioning from other coverage who are currently prescribed Part D drugs not on the new Part D plan's formulary. The purpose of this period is to transition the new enrollee to a therapeutically-substitutable formulary drug or, alternatively, to obtain a formulary exception whereby the new Part D plan would continue to cover the non-formulary drug for the remainder of the plan year for reasons of medical necessity.

Similarly, we proposed requiring MA organizations to continue to ensure access to DME brands, items and supplies of non-preferred manufacturers—such as diabetic test strips—for a transition period comprising the first 90 days of coverage under the plan, as specified by CMS. Similar to the Part D transition process, we expect that MA organizations would provide one refill during the 90-day transition period. We also propose requiring that, during this 90-day transition period, MA organizations cover repairs to DME brands, items, and supplies of non-preferred manufacturers such as wheelchairs, feeding pumps, and hospital beds. More specifically, the enrollee, during this 90-day transition period, could elect to have the MA plan continue to provide the DME brand, item or supply from the non-preferred manufacturer as well as provide all necessary repairs to DME items, including providing a loaner. Alternatively, the enrollee could immediately switch to a brand, item, or supply of a preferred manufacturer. We reflected this change in proposed § 422.100(l)(2)(iii)(A) and § 422.100(l)(2)(iii)(B).

Comment: In the proposed rule we recommended a 90-day transition period to enable beneficiaries who had used one brand of DME and had to change brands because their current plan no longer supplies this brand, to adjust to the change. We solicited comments on the duration of the transition period. While we received comments that indicated no transition period was necessary, other commenters agreed with the 90-day transition period, others suggested durations of 120 days and 6 months.

Response: We believe that the proposed 90-day transition period, similar to the transition period in the Part D program, strikes the appropriate balance between ensuring an enrollee's smooth transition to a new plan while taking into account the ability of the plan to offer preferred DME items for its enrollees.

Comment: We also received several comments on the appropriateness of a transition period. A commenter pointed out that it should not be required for enrollees to continue a former DME brand if new brands were more efficacious. Another commenter asked if the use of a brand, item, or supply from a non-preferred manufacturer based on a medical-necessity determination only applies to the transition period.

Response: Our requirement that plans continue to furnish non-preferred DME brands that they had formerly was not intended to prevent a plan enrollee from switching to a different brand, should she or he so desire. If the enrollee wants to continue using the former brand, item, or supply, the new plan must furnish it for 90 days. Alternately, the enrollee may decide to change brands immediately. We also note that the medical necessity exception and the transition exception are independent of one another. An enrollee is permitted a 90-day transition period for a currently non-preferred brand that was used in the former plan year even if that non-preferred brand is not considered medically necessary for that individual.

Furthermore, if deemed medically required, the new plan is required to furnish the specific DME brand, item, or supply regardless of whether the product was used previously.

d. Midyear Changes to Preferred DME Items and Supplies

We proposed prohibiting MA organizations from making ''negative changes,'' that is, eliminating coverage of a Medicare-covered DME brand, item or supply of a preferred manufacturer, midyear. However, plans would not be responsible for involuntary negative changes such as those due to supplier terminations or sanctions. We also proposed allowing MA organizations to make ''positive changes,'' that is, adding coverage of Medicare-covered DME brands, items or supplies, midyear. Examples of allowable positive midyear changes include: Adding new manufacturers' products, providing substitute DME brands, items and supplies for DME products that are no longer available, considering new DME technologies, and complying with national and local coverage determinations for new DME brands, items and supplies. Plans could also add suppliers midyear. We believe this strikes the appropriate balance between allowing flexibility for plans to designate preferred products, while ensuring that changes to the list of DME brands, items and supplies of preferred manufacturers are not disruptive to enrollees. We reflected this change in proposed § 422.100(l)(2)(iv).

Comment: We received several comments on midyear changes to DME. A number of commenters criticized the proposed rule on the grounds that it would not be sensitive to midyear changes in technology. Other commenters raised the issue of the effect of supplier termination or supplier sanctions. Still other commenters asked if suppliers as well as products could be added midyear.

Response: In the proposed rule we allow the addition, but not the deletion, of brands and manufacturers midyear. Consequently: (1) Plans may add DME with innovative new technologies midyear; and; (2) plans may add midyear suppliers as this would increase brands and manufacturers available to enrollees. Note, that if a midyear supplier termination or supplier sanction deprives enrollees of access to certain brands, items or supplies of preferred manufacturers, the plan has an obligation to add suppliers midyear in order to maintain enrollee access.

Comment: A commenter requested that plans be allowed to withdraw midyear brands and manufacturers based on safety issues.

Response: We agree that plans must exclude items from their preferred DME list if recalled by a Federal agency, for example, the FDA, or if CMS determines there is a safety concern. Additionally, if a plan has concerns regarding the safety of a certain brand or manufacturer, it should immediately contact the FDA's Center for Devices and Radiological Health Ombudsman to whom such concerns should be directed.

e. Appeals

As indicated previously, a medical necessity determination is initiated by the enrollee's provider. The plan's subsequent denial could then lead to an appeal or expedited appeal. We proposed to clarify at § 422.100(l)(2)(v) that a plan's non-coverage of a particular manufacturer's product or brand of a DME constitutes an organization determination under § 422.566.

Comment: Several commenters requested that to ensure a proper balance between costs and access, CMS must incorporate safeguards around the use of DME formularies similar to those of Part D drug formularies. These commenters specifically identified the following Part D safeguards as examples of safeguards that should apply to DME: (1) Annual review and approval of DME formularies established by Medicare Advantage Plans by the plans' respective Pharmacy and Therapeutics Committees; (2) a formal exceptions process for non-formulary DME items deemed medically necessary for a particular patient, similar to that employed for Part D drugs pursuant to § 423.578; and, (3) the right of patients to seek review of adverse determinations related to requested DME brands, items or supplies by an independent review entity in a manner similar to that utilized for adverse determinations made by Part D Plans related to Part D drugs.

Response: As indicated in the proposed rule, we studied the possibility of establishing an exceptions process for DME similar to the one established for non-formulary Part D drugs under § 423.578(b) and decided that the safeguards we proposed, along with the ability to appeal brand/manufacturer decisions as coverage determinations, were the most efficient means to implement this provision in the context of the MA program. The Part D appeal process adds an additional level of review to the established appeal process under subpart M of Part 422 to account for the fact that Part D drugs in a category of prescription drugs are frequently prescribed based on the individual's unique requirements and disputes about medical necessity are more likely. We believed such a process is unnecessary for DME brands, items and supplies because, unlike Part D drugs, DME is generally not specific to individuals and, as a result, appeal of coverage determinations based on brand/manufacturer are infrequent.

Comment: A few commenters requested that, in addition to the right to appeal non-coverage of non-preferred, medically-necessary DME, CMS issue guidance on differential cost-sharing between preferred and non-preferred brands.

Response: As specified in § 422.100(f)(2), MA plans are already prohibited from designing cost-sharing structures that inhibit access. We annually publish detailed guidance on acceptable cost-sharing criteria.

Comment: Several commenters requested that we provide guidance, similar to guidance in the Part D program, on the criteria for making an Independent Review Entity (IRE) determination. These commenters also recommended that access to DME and medical necessity be guiding principles as part of the IRE determination process.

Response: We agree that access and medical necessity should be two primary principles guiding IREs in making determinations. For this reason, we strongly encourage MA plans when formulating their medical-necessity requirements, as specified at § 422.112(a)(6), to specifically address how medical-necessity determinations by enrollee providers should be communicated and addressed. We do not believe it necessary, however, that IREs be given additional guidance regarding how to determine claims based on the brand/manufacturer of DME.

Comment: In the proposed rule, CMS supported our decision not to have a formal exception process for DME denials by citing the following statistic: Of 12,500 appeals on wheelchairs reviewed by the IRE since the inception of the IRE appeals process in 2006, only seven related to brand-specific issues. A commenter suggested that the small number of brand-specific appeals could be due to our not formerly allowing plans to limit DME items, such as wheelchairs, by brand and manufacturer.

Response: As indicated in the proposed rule, we have anecdotal evidence that plans are already limiting DME by brand and manufacturer. Consequently, we believe this statistic to be supportive of our proposal.

f. Disclosure of DME Coverage Limitations

As provided under § 422.111(b)(2), MA plans must notify enrollees—at the time of enrollment and annually thereafter—of the benefits offered under the plan, including applicable conditions and limitations, premiums, and cost-sharing, and any other conditions associated with receipt of benefits. This requirement has been operationalized as the annual notice of change/evidence of coverage (ANOC/EOC). We would require, under proposed § 422.100(l)(2)(vi), that MA plans that choose to limit DME coverage to brands, items, and supplies of preferred manufacturers, be required to include, in the description of benefits required under § 422.111(b)(2) and under § 422.111(h)(2)—which requires the provision of specific information via a toll-free customer service call center and Internet Web site, and in writing upon request—disclosures about these DME coverage restrictions and enrollee rights to the Part C appeals process for requests to obtain medically necessary DME brands, items, and supplies from non-preferred manufacturers.

Comment: Several commenters requested clarification on how MA organizations should disclose the list of DME brands, items, and supplies of preferred manufacturers. For example, several commenters asked whether they should be listed in the bid or EOC. These commenters pointed out that the EOC is a template and consequently a template change would be required for additional disclosures. Other commenters asked whether these materials should be listed on plan Web sites or in the plan finder.

Response: As specified in § 422.111(b)(2) and § 422.111(h)(2), MA plans must disclose all conditions, limitations, premiums, and cost-sharing for benefits they provide, including DME. There are already several vehicles for such disclosure in place. We propose modeling the disclosure requirements for DME by applying similar disclosure requirements currently used for the Part D formulary. More specifically, a plan choosing to limit certain DME products to specific brands and manufacturers would have to maintain a Web site with current information on DME access. We would also require that the list of DME brands, items, and supplies of preferred manufacturers be included in the EOC packet. We will issue guidance on these matters along with other guidance for proper bid submission.

Comment: A commenter requested that disclosure requirements apply to any changes in provision of DME such as midyear changes. Another commenter asked if providing access to only two brands is a limitation for which notification is required.

Response: We are modeling the disclosure requirements for DME on the disclosure requirements for the Part D formulary. Consequently, in addition to the list of brands, items, and supplies of preferred manufacturers that should be mailed in the EOC packet along with the Part D formulary, MA plans must have dedicated Web sites listing all current information on DME provision, including any midyear changes. Plans must notify enrollees of any contractual limitation in DME brands, items, supplies, and manufacturers.

Comment: A commenter requested a 60-day notification for any midyear changes.

Response: The notification requirements for midyear changes specified in the Medicare Marketing Guidelines are applicable to midyear changes in DME.

Comment: A commenter asked whether plans must submit their DME formularies, that is, their list of brands, items, and supplies of preferred manufacturers, to CMS for prior approval.

Response: As indicated in the proposed rule, we are not applying the formulary requirements of the Part D program in our DME policies. Consequently, the submission of bids that includes all supporting documentation as part of the annual bid review cycle will suffice.

g. Flexibility

Based on comments we received on the proposed rule, and which we discuss later in this final rule with comment period, we are providing additional flexibility at 422.100(l)(2)(vii) for CMS to annually review DME categories. We would also review complaint data and appeals and grievances data. This would allow us to require full coverage of certain categories of DME without limitation in brand and manufacturer. Additionally, such flexibility would allow us to consider and respond to emerging new technologies, as well as to require full coverage of categories of DME items typically tailored to meet individual needs.

Comment: Several commenters requested that we exclude orthotics and prosthetics from the items that MA organizations could limit purchase of to specific brands and manufacturers. Several commenters requested a general exclusion of orthotics and prosthetics while other commenters requested exclusion of specific orthotics and prosthetics. In particular, several commenters pointed to our use, in the proposed rule, of ostomy bags as an example of an item that could be subject to limitation based on brand or manufacturer. One of the commenters asked if we had intended to include ostomy bags, as they are actually prosthetics. The other commenters on this issue, while not identifying ostomy bags as prosthetics, stated that these are not, in fact, examples of items that are interchangeable and, thus, should not be subject to limitation based on brand or manufacturer.

Response: When discussing the transition requirement, we mistakenly included ostomy bags, which are prosthetic devices, in our example of DME that would be subject to limitation—and thus the transition requirement—based on brand or manufacturer. In discussing the transition requirement, a better example would be diabetic supplies. In this final rule with comment period, we are clarifying that the ability of MA organizations to limit DME brands, items, and supplies to specific manufacturers does not apply to orthotics and prosthetics. Section 1860(s) of the Act specifically distinguishes the authorities for provision of DME, prosthetics and orthotics. Consequently, our proposal to allow plans to limit provision of DME brands, items, and supplies to specific manufacturers would not affect prosthetics and orthotics. MA organizations must still provide to their enrollees all medically-necessary prosthetics and orthotics covered under Original Medicare, Part B. The principal reason for not including orthotics and prosthetics in the scope of this requirement is that the provision of orthotics and prosthetics requires clinical care by specially educated and trained practitioners who utilize those skills to design, fabricate, and fit custom orthoses and prosthesis. DME, however, primarily refers to equipment such as wheelchairs (manual and electric), walkers, scooters, canes, crutches, and home oxygen therapy. A standard cane from a supplier, for example, is qualitatively different from receiving a custom-fit orthotic brace molded specifically for the patient by a skilled provider. We already recognize this distinction between DME and prosthetics and orthotics in its quality and supplier standards.

Comment: There was support for the notion that brands of certain DME such as canes are essentially interchangeable. However, over half the commenters mentioned specific categories of DME whose brands are less likely to be interchangeable in terms of quality, consistency in performance, and ease in repair. Among the 43 comments received, 7 categories of DME were identified for which commenters requested full coverage without plan limitation: (1) Wheelchairs; (2) diabetic supplies; (3) Continuous Positive Airway Pressure (CPAP) devices; (4) patient lifts; (5) speech generating devices; (6) oxygen; and (7) paddings (such as foam mattresses). Additionally, a commenter questioned the classification of speech-generating devices as DME, rather than orthotics and prosthetics, citing the Department of Defense and VA classifications.

Response: We agree that certain categories of DME include items which are tailored to the individual and are not interchangeable. For this reason, we intend to conduct an annual review to ascertain which categories or subcategories of DME require full coverage without allowance for plan limitation by brand or manufacturer. In making our decisions, we will identify categories of DME not subject to limitation, based on a variety of sources. Sources include, but are not limited to—

- Comments on the proposed rule;
- Discussions with DMEPOS staff;
- Advice from the Chief Medical Officer Center for Medicare, CMS and DME MAC medical directors; and
- Experience from the DMEPOS competitive bidding program and other Medicare programs.

Based on our review of public comments, we have modified our proposal by adding new paragraph (l)(2)(vii) to § 422.100 to specify that plans must comply with CMS' designation of DME items not subject to limitation based on brand or manufacturer.

We have made two other changes to the regulatory text: (1) at 422.100(l)(2)(iii) we have clarified that transition coverage changes are at the enrollee's request; and (2) throughout the regulatory text we use the phrase ''DME brands, items, and supplies of preferred manufacturers.'' The enrollee's request for transition coverage is initiated when he or she fills a script and generates a claim for a particular brand. Our purpose in using the phrase ''DME brands, items, and supplies of preferred manufacturers,'' is to emphasize that plans can limit both items and supplies and plans can limit by either: brand, manufacturer, or both.

Following this discussion are several comments that address more general issues related to the proposed rule.

Comment: A few commenters were opposed to the proposed rule on general grounds. They cite section 1801 of the Act which prohibits supervision over the practice of medicine and section 1802 of the Act which guarantees basic freedom of choice. Another commenter disagreed with our authority to allow plans to limit brands and manufacturers, arguing that section 1852(a)(1)(A) of the Act, allowing MA plans to contract with networks of providers, specifically applies to providers, not suppliers.

Response: In the proposed rule—and as clarified further in this final rule with comment period—we have specifically indicated that a medical-necessity determination by the enrollee's provider initiates a process that could allow enrollees access to DME brands, items, and supplies of non-preferred manufacturers. Hence, we have not interfered with the practice of medicine. Furthermore, section 1852(a)(1)(A) of the Act specifically allows plans in the MA program to limit the providers from which services may be obtained, provided adequate access is ensured. The statute is silent on limitations of supplier networks. As we stated in the proposed rule, we believe it is consistent with the goals of the statute to allow MA plans to contract with networks of suppliers and to restrict brands and manufacturers provided access is ensured and are thus exercising our authority under 1856(b)(1) of the Act, to establish MA standards by regulations, and section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate.

Comment: A commenter believed that the proposed regulation had given plans arbitrary power and would unnecessarily limit beneficiary choices. The commenter also believed that MA plans do not have the necessary knowledge to make decisions about limits on brands, items, supplies, and manufacturers of DME. Another commenter asked how CMS would define access to non-preferred brands.

Response: In developing our proposal, we took deliberate steps to ensure that an MA organization's DME polices not be instituted arbitrarily and that such policies are fair and transparent to enrollees. In the proposed rule, we specifically mentioned our goal to strike ''the appropriate balance between allowing flexibility for plans to designate preferred products, while ensuring that changes to preferred DME products are not disruptive to enrollees.'' Furthermore, we explicitly proposed at § 422.100(l)(2)(ii), that MA organizations—to the extent that they elect to limit coverage of DME items and supplies to specific manufacturers' products or brands—ensure access to DME by providing coverage of any medically-necessary DME brand, item, and supply, including DME brands, items, and supplies made by non-preferred manufacturers. Other requirements, such as the transition period and the prohibition on removing DME items midyear, also help ensure that enrollees will continue to have full access to DME.

Comment: A few commenters requested that we offer the proposed rule as guidelines rather than regulations. These commenters suggested that, aside from specific requirements to ensure adequate access, we should not impose requirements or otherwise oversee functions that have traditionally been left to the discretion of plans.

Response: We have already given plans much flexibility in choosing DME; we must also ensure that enrollees continue to have access to necessary DME. Plans must develop their own medical necessity criteria and methods for addressing provider determinations of medical necessity. However, the requirements delineated in the proposed rule, including disclosure, beneficiary appeal rights and access, have traditionally been regulatory areas and part of CMS' oversight of plans. In the proposed rule, we proposed requirements in three other areas—medical necessity, transition periods, and midyear changes—and believe these to be important beneficiary protections.

Comment: A commenter pointed out that, although the proposed rule focuses on reducing out-of-pocket costs for beneficiaries, this concept could also affect costs for plans.

Response: In the proposed rule we pointed out that some organizations are already limiting DME to specific brands; consequently, our proposal would not adversely affect the costs incurred by these organizations. As we stated in the proposed rule, we believe this provision will give more flexibility to plans when making DME choices; if plans wish to offer multiple brands of DME in a category, this provision would in no way prohibit this. As we also stated in the proposed rule, we believe this additional flexibility may permit MA organizations to negotiate bulk discounts with preferred manufacturers.

Comment: Several commenters pointed out that cost savings was the only reason mentioned in the proposed rule to allow plans the right to limit furnishing DME to specific brands and manufacturers. Another commenter mentioned an MA plan that is currently selecting manufacturers and brands of diabetic supplies, based on consultation with clinicians and, consequently, is able to offer products at zero cost-sharing to its enrollees.

Response: We agree that a variety of factors—including cost, access, diverse patient needs, convenience, and medical necessity—should be part of benefit considerations and overall plan design. We believe the beneficiary protections we have specified concerning enrollee access to all categories of DME will help ensure that cost is not the sole driving factor of a plan's DME choices. In addition, we believe that quality requirements, a robust appeals process, and plan oversight are important factors in ensuring that enrollees have continued access to necessary DME.

Comment: Several commenters requested that if an individual requires multiple DME brands, items, or supplies and one brand, item, or supply that he or she requires is only available through a supplier of brands, items, and supplies from non-preferred manufacturers, the individual should be allowed to obtain all the medically-necessary brands, items, and supplies from the non-preferred manufacturer. This would promote efficiency and ease of obtaining brands, items, and supplies.

Response: The implication of this comment is that it is inconvenient for the enrollee to have to purchase brands, items, and supplies from multiple suppliers. We do not agree. Furthermore, since MA organizations contract with suppliers, they can communicate in advance the brands and manufacturers that are preferred and nonpreferred so that suppliers can stock up on these.

Based on our review of public comments, we are finalizing our proposed provisions with the modifications previously discussed.

5. Broker and Agent Requirements (§ 422.2274 and § 423.2274)

Regulations setting forth rules for agent and broker compensation promulgated in our November 10, 2008 interim final rule with comment (73 FR 67406 through 67414) required MA organizations and Part D plan sponsors (''plan sponsors'') to submit historical agent/broker compensation data from years 2006 and 2007. In addition, we requested that plan sponsors submit information in 2008 that would indicate their 2009 compensation schedules for agents selling Medicare health plans on their behalf. We conducted an analysis of the historical compensation information submitted by plan sponsors and published fair market value cut-off (FMV) amounts during the spring of 2009. Later that year, plan sponsors were given the opportunity to adjust their compensation amounts to any amount at or below the FMV. These adjusted 2009 amounts became the baseline amount for compensation adjustments in future years. Subsequent to our initial compensation guidance, plan sponsors have expressed concerns about the validity of continuing to base future compensation on amounts which were selected in 2009 and based on data from 2006 and 2007.

We have also heard that current economic conditions have drastically changed local markets such that, even as adjusted, the 2009 compensation amounts do not accurately reflect the current market rates. We have been advised by plan sponsors that have been in the market since 2009 that they are at a competitive disadvantage as compared to newly entering plans as the new entrants may set compensation at current-day FMV rates and are not tied to 2009 compensation amounts. Therefore, we proposed to modify paragraph (a) and add a new paragraph (f) to § 422.2274 and § 423.2274 to allow plan sponsors to annually select their compensation amounts to reflect rates which are at or below FMV as annually established by CMS. Under these proposed changes, plan sponsors would also be required to report their intentions to use independent agents and/or brokers in the upcoming plan year, along with the amounts that they will be paid, if applicable.

Comment: Many commenters expressed support for the proposal to allow sponsors to annually select agent/broker compensation amounts which reflect rates at or below the CMS established FMV.

Response: We appreciate the many comments received in support of this provision.

Comment: A commenter asked whether this provision applies to section 1876 cost plans.

Response: This provision does apply to section 1876 cost plans pursuant to § 417.428, Marketing Activities, which states that the marketing regulations found in subpart V of part 422, which include this specific requirement, apply to section 1876 cost plans.

Comment: A commenter expressed a concern that the compensation regulations were driving agents/brokers away from MA and encouraging them to sell Medigap.

Response: We appreciate the comment and will consider it as we continue to refine and improve our managed care programs. However, this comment is beyond the scope of these regulations.

Comment: Several commenters expressed a concern that CMS should be evaluating its current marketing rules against the Affordable Care Act and considering the impacts.

Response: We appreciate the comment and will consider it as we implement the provisions under the Affordable Care Act. However, these comments are beyond the scope of this regulation.

After consideration of the public comments received, we are finalizing the provision without modification.

6. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.100, § 423.104, and § 423.153)

Pursuant to our authority under section 1860D–4(c) of the Act, which requires PDP sponsors to have cost-effective drug utilization management and a fraud, abuse, and waste control program in place, we proposed that Medicare Part D sponsors be required to provide their enrollees access to a daily cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days' supply of certain covered Part D drugs that: (1) Are for an initial fill of a new medication; (2) are intended to allow the enrollee to synchronize refill dates of multiple drugs; or (3) are dispensed in accordance with § 423.154 (which sets forth the requirements placed on Part D sponsors with respect to dispensing of prescription drugs in long-term care facilities beginning January 1, 2013).

As we explained in the proposed rule, current prescribing patterns and pharmacy benefit management (PBM) payment practices result in most prescriptions being written by providers, and dispensed by retail pharmacies, in 30-or-more days quantities. When the full amount dispensed is not utilized by a beneficiary due to adverse medication reaction or interaction, or due to failure of beneficiary therapeutic adherence because of cost, inconvenience, death, or other reason for discontinuation, it comes at an unnecessary and wasteful cost to the beneficiary, the Medicare program, Part D sponsors, and the environment.

We believe that if Part D enrollees and their prescribers had the option of shorter days' supplies of initial fills of new prescriptions, without the disincentive of the enrollee having to pay a full month's (or longer) copayment or coinsurance, a significant portion of the current costs to the program of chronic medications discontinued after initial fills could be avoided. In addition, the avoidance of unused drugs would contribute to diminishing the environmental issues [2] caused by disposal of unused medications, and opportunities for

[2] See *http://www.epa.gov/ppcp* for information about Pharmaceuticals and Personal Care Products as Pollutants (PPCPs) on the Web site of the U.S. Environmental Protection Agency.

criminal activities and substance abuse [3] caused by diversion of unused medications, all of which are growing concerns in the United States.

We observed that, currently, Part D enrollees' cost-sharing generally is the same whether they receive a 7, 14, or 30 days' supply of a medication. A daily cost-sharing rate requirement imposed on Part D sponsors would encourage enrollees and their prescribers to limit days' supplies, when appropriate, by reducing the enrollees' out-of-pocket costs. More specifically, under our proposal, Part D sponsors would be required to establish and apply a daily cost-sharing rate, such that an enrollee requesting a trial fill of a prescription for a new chronic medication, for example, would pay only a portion of the established cost-sharing amount under his or her Part D benefit plan that corresponds to the actual number of days supply that was dispensed. This would be the case whether it was for a 7- or 14-days' supply, or some other quantity less than 30 days, and this decision would primarily be at the discretion of the prescriber. Thus, although a daily cost-sharing rate requirement would be mandatory for Part D sponsors, actually taking advantage of it would be voluntary for enrollees and their prescribers. Neither sponsors nor the Federal government would determine whether a beneficiary should receive less than a month's supply of a new medication. Rather, such a decision should be made solely by the beneficiary and his or her prescriber.

Through the establishment and application of a daily cost-sharing rate requirement on Part D sponsors, we believe an enrollee would be especially incentivized to inquire of his or her prescriber whether a fill of less than a month's supply would be appropriate when first prescribed a chronic medication. We also believe enrollees would be most likely to inquire about such a trial fill when faced with high cost-sharing for such a medication, due to the expense of the drug, such as when purchasing a drug in the deductible phase of the benefit or in the coverage gap. We further believe prescribers would be most likely to concur as to the appropriateness of a trial fill when the prescription is for a drug that has significant side effects and/or is frequently poorly tolerated.

In such a case, we suggested that the prescriber could write either one prescription for the initial fill at the prescriber's discretion, or two prescriptions (for example, one for an initial fill and a second prescription for a 30 or 90 days' supply; the latter prescription would be utilized if the enrollee and the prescriber agreed the drug therapy should be continued after the trial period). Because the two prescriptions could be written during one office visit, or could be refilled by the prescriber directly with the beneficiary's pharmacy after the trial period, as permitted by applicable law, additional visits to the prescriber would not necessarily be required and would not need to cause a burden to the beneficiary. We assumed the two-prescriptions option would be most convenient for the beneficiary and the prescriber (when appropriate), but sought specific comment on this assumption. If a beneficiary would have difficulty returning to the pharmacy, presumably he or she would not inquire about a trial fill. Furthermore, since prescribers would determine whether or not medication being prescribed should or could be dispensed in a trial fill, we stated that we would not expect our proposal to have any adverse effects on beneficiaries' health. However, if the medication were discontinued after use of the initial fill, the enrollee, as well as the sponsor, would have avoided the net costs associated with the unused quantity that would be dispensed under current standard practices.

While we envisioned, as described previously, beneficiaries primarily requesting less than a full month's supply when prescribed a drug for the first time for a chronic condition that is known to have significant side effects, to be frequently poorly tolerated and expensive, we did not limit the requirement for Part D sponsors to establish and apply a daily cost-sharing rate to such medications. Rather, in the proposed rule, we also identified an additional benefit of a daily cost-sharing rate requirement, which is the ability to allow for synchronization of prescriptions. The ability to synchronize medications should assist beneficiaries in adhering to prescription treatment regimens that involve multiple medications, and we noted that at least one study supports this belief. In addition, we believe the ability to synchronize medications will be convenient for both those beneficiaries who take advantage of it and their prescribers by enabling fewer trips to the pharmacy and fewer prescription refill requests of prescribers from beneficiaries through the ability to consolidate pharmacy trips and prescriber office visits and phone calls. We also stated that daily cost-sharing rates also may permit pharmacies, as opposed to prescribers, to facilitate synchronization of a beneficiary's medications upon his or her request, and we sought specific comment as to this possibility, as well as to any issues we may need to address to facilitate this possibility.

We noted in the proposed rule that we do not expect long-term care (LTC) beneficiaries to request to synchronize medications, as this was not our understanding of the LTC environment with respect to prescribing, and the LTC dispensing rules at § 423.154 require 14 days or less dispensing in LTC facilities in certain instances, beginning January 1, 2013. However, as noted in the April 2011 final rule (76 FR 21432), we expected the LTC dispensing requirements ''would likely lead to a change in copayment methodology * * * [and] anticipate[d] the implementation of particular copayment methodologies will be dependent on the billing and dispensing methodologies used, and as a result * * * copayment methodologies within the same plan may vary depending on the LTC facility where the beneficiary resides. Copayment may be collected at the first dispensing event in a month, the last dispensing event in a month, or prorated based on the number of days a Part D drug was dispensed in a month. However, due to the relatively small copayments for low-income subsidy (LIS) beneficiaries, copayments for LIS beneficiaries should be billed with the first or last dispensing event of the month.'' Because Part D sponsors would have to address copayment methodology in connection with the LTC dispensing requirements, we proposed to supersede our quoted guidance in the April 2011 final rule (76 FR 21432), and thus proposed that the daily cost-sharing rate requirement would apply to prescriptions dispensed in LTC facilities, beginning January 1, 2013.

In the proposed rule, we urged the industry to develop coding to be used by network pharmacies to communicate to sponsors whether a less than month's fill is to align refill dates, or for that matter, is an initial fill of a new medication, or in the case of the LTC setting, is to communicate the dispensing methodology employed. We stated such coding would allow

[3] See Office of National Drug Control Policy, 2008 ''Prescription for Danger'', January 24, 2008, and 2009 National Drug Survey on Drug Use and Health (NSDUH), September 2010, for more information on the growing problem of nonmedical use of prescription drugs in the United States, particularly among teenagers. See also *http://www.deadiversion.usdoj.gov/index.html* for more information from the Drug Enforcement Administration about the problems associated with drug abuse resulting from legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic.

sponsors to be able to monitor the prevalence and appropriateness of the dispensing of prescriptions in shorter than a month's supply to ensure that a pharmacy does not dispense a prescription for 30 days' supply in stages in order to increase dispensing fees.

We recognized in the proposed rule that establishing and applying a daily cost-sharing rate to the already small copayments for LIS beneficiaries would cause such copayments to be the same or even smaller. We also stated that, while there may be additional waste generated by multiple fills when medications are continued or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables.

We acknowledged in the proposed rule that realized savings from our daily cost-sharing rate proposal may be partly offset by additional dispensing fees, and that Part D sponsors would also incur some costs to program their systems to establish and apply a daily cost-sharing rate to prescriptions dispensed to enrollees for less than a 30 days' supply. We cited in the proposed rule a previous review of 2009 PDE data by us that suggested that just under 32 percent of approximately 78.6 million first fills for chronic medications are not refilled by Medicare Part D enrollees. We assumed for purposes of estimating savings to the Part D program that the lack of refills indicates the prescribed medications were discontinued. The estimated total cost of these discontinued medications was approximately $1.6 billion (70 percent for brands and 30 percent for generics). However, since this review did not distinguish between community and institutional settings, to estimate the costs of discontinued medications in community settings only, we reduced the total costs by approximately 13 percent in accordance with CMS data on gross drug costs in the Part D program in 2009 in the community and institutional settings to remove a proportion representing long-term care expenses. (We did not estimate the costs of discontinued medications in the LTC environment since the daily cost-sharing rate requirement proposed here does not further change the dispensing requirements in the long-term care setting, which are applicable January 1, 2013). Consequently, we arrived at an adjusted total estimated cost of 2009 community-based discontinued first fills of maintenance chronic medications was estimated at roughly $1.4 billion.

As noted previously and in the proposed rule, potential savings of a daily cost-sharing requirement on Part D sponsors would come from a reduction of these costs which would be offset by some additional dispensing fees. In order to estimate the savings, we made assumptions about how many initial fills for new maintenance medications for chronic conditions will be dispensed in quantities of less than a 30 days' supply, and what the average quantity of such initial fills will be. We pointed out that these assumptions were highly uncertain, because it is very difficult to predict beneficiaries' behavioral response. Having noted this caveat, we assumed 20 percent of initial fills in 2013 will be for a supply of less than 30 days, trending to almost 50 percent by 2018, and that the average of such fills will be for a 15 days' supply. We also applied a dispensing fee rate of approximately $2 in our estimation. Assuming 32 percent of these first fills are discontinued, we estimated the potential savings to the Part D program to be $140 million in FY 2013 alone, and over $2.4 billion total by 2018. However, because we are revising the applicable date of this requirement to January 1, 2014, as explained later in this final rule with comment period, we are revising the cumulative savings in 2018 to roughly $1.8 billion.

We noted in the proposed rule that we considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and required to be dispensed in a 15-day initial script to ensure cost effectiveness without wasting or discarding of dispensed, but unused, medications. We have learned through representatives of the program that MaineCare has achieved overall savings for 2 consecutive State fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there has been very good acceptance of the program and very little confusion upon implementation. While we acknowledged the savings benefits of the mandatory MaineCare approach, we stated that leaving the decision to obtain less than a month's supply of a prescription with the beneficiary and his or her prescriber and pharmacist is a better approach in light of the voluntary nature of the Medicare Part D program.

We recognized in the proposed rule that certain medications are universally accepted in the health care community as not suitable to be dispensed in amounts less than a 30 days' supply (for example, lotions and other drugs not in solid form). Therefore, we proposed to further limit the requirement that sponsors establish and apply a daily cost-sharing rate to solid oral doses of drugs, except antibiotics or drugs which are dispensed in their original containers as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, steroid dose packs). However, unlike the long-term care dispensing requirements, we proposed that the daily cost-sharing rate requirement would apply to both brand and generic drugs.

Comment: Some commenters were strongly supportive of our proposal, recognizing as we do that, for Part D plans that use a copayment structure, there is currently no direct cost incentive for enrollees to obtain a less than 30 days' supply, and lauding the potential cost-savings to enrollees and the reductions of waste as a result of our proposal. A commenter fully endorsed our proposal, stating that its data led to the MaineCare program, and that after significant effort was put into addressing initial prescriber confusion, there were virtually no complaints by either prescribers or patients. This commenter disagreed, however, that a voluntary approach is the preferred method, asserting that clinical inertia for continuation of past prescribing habits and practices may erode our expectations on savings. A commenter estimated that our proposal could eliminate 1.5 billion pounds of pharmaceutical waste at its source (the preferred method for improving environmental health) and $1 million in waste management cost savings, in addition to improving dispensing efficiencies in terms of time spent. A commenter asserted that an analysis of our proposal regarding the harmful effects on the environment should include recognition that humans are part of the environment and are adversely affected by the diversion, misuse, and abuse of unused drugs.

Response: We appreciate these supportive comments and estimates and agree that a daily cost-sharing requirement will lead to significant cost-savings and waste reduction in the Part D program. We have taken the comments on prescriber education under advisement, but we continue to believe that the voluntary method is the best way to approach less-than-30-days' supply dispensing outside the LTC setting in the Part D program, although we acknowledge our opinion could change after experience with the voluntary method. We agree that reducing medication waste will reduce opportunities for medications to be diverted for misuse and abuse.

Comment: Some commenters stated that we should complete a more thorough, and prospective assessment of the potential impact of our proposal to understand the tradeoffs and implications before we proceed with it. Several commenters, while supporting our proposal's goal to reduce cost and waste, countered that it would increase dispensing fees and administrative and programming costs, some suggesting that these fees/costs would completely or more than offset any realized savings from the proposal. Another commenter stated that calculating the daily cost-sharing rate for each enrollee is tremendously burdensome by necessitating system changes at a substantial cost, stating that the administrative costs to Part D sponsors are the same regardless of whether the prescriber writes a prescription for a trial fill or a 30 days' fill, such that administering a trial fill differently than a complete fill will double the cost to Part D sponsors.

Response: We believe that we have sufficiently accounted for the tradeoffs and implications of the potential impact of our requirement, both in the proposed rule and in this final rule with comment period. In the preamble and the Regulatory Impact Analysis section of the proposed rule and this final rule with comment period, we specifically accounted for the additional dispensing fees, as well as the administrative and programming costs that we believe Part D sponsors will incur in implementing this requirement. Despite these costs, we continue to estimate savings in the hundreds of millions each year to the Part D program.

Comment: Some commenters, while also supportive our of proposal's goal to reduce fraud, waste and abuse in the Medicare Part D program, raised various operational concerns in implementing the proposal and requested a delay or phased-in approach. A commenter requested more clarification of what constitutes a trial fill. Some commenters recommended that we simplify our proposal by requiring the application of the daily cost-sharing rate whenever less than a month's supply of a covered Part D drug is dispensed (unless an exception applies due to the type of drug involved), regardless of the reason, which would obviate the need to document the reason. Some commenters stated that applicable law permits pharmacists to dispense lesser quantities than written on certain prescription. Other commenters indicated that standard identifiers/fields would be needed for physicians, pharmacies, and plans to communicate regarding initial fills of new medications, beneficiary synchronization request and daily cost-sharing amounts. Some commenters pointed out that pharmacies have no reliable way to learn that a prescription is an initial trial supply of a new medication, since such information is not routinely conveyed on a prescription, and pharmacies would not be in a position to notify sponsors of this fact, even if coding were available.

Another commenter believed that having to capture information from enrollees could be difficult to reliably implement. Some commenters thought that our proposal would result in more frequent ''refill too soon'' DUR edits, including additional PDEs identified as duplicate, requiring review and justifications, which would result in greater workload for Part D plans. Commenters also noted that daily cost-sharing is not an industry standard in prescription drug coverage, and complications could arise in coordinating benefits with other prescription drug plans, such as in the case of Employer Group Waiver Plans (EGWPs). A commenter stated that our proposal may result in multiple prior authorizations for the same medication. A commenter noted that our proposal may complicate partial fill straddle claims and have PDE and TrOOP implications. A few of these commenters noted that lessons may be learned from implementation of the long-term care dispensing requirements at § 423.154, which are effective January 1, 2013.

Response: We were persuaded by these commenters that more time is needed for Part D sponsors, PBMs, their network pharmacies, and industry standard development organizations to work through the details of implementation of our requirement. We believe that proper programming will be crucial to address the technical issues that the commenters referenced, such as how to calculate cost-sharing when multiple payers are involved. For these reasons, we have delayed implementation of the daily cost-sharing rate requirement until January 1, 2014. In addition, we will work with the industry to develop subregulatory guidance, if and as needed, to address technical questions arising upon implementation of the requirements, such as the implications for PDE submissions.

However, to the extent Part D sponsors wish to implement daily cost-sharing rates for contract year 2013, they may do so on a voluntary basis before then, for instance, if such implementation would assist them in complying with the LTC dispensing requirements, rather than waiting for any lessons that may be learned from such implementation, since Part D sponsors will have to address cost-sharing with respect to LTC dispensing in 2013.

In deciding to delay implementation of these requirements for 1 year, we were also persuaded by comments that we should simplify our requirement and apply it to all drugs dispensed for less than a month's supply. Without this simplification of the requirement, we agree that extraordinary processes would have to be created to obtain information about the reasons less than a month's supply is being dispensed. For instance, the parties involved in the prescription transaction (for example, health plans, PBMs and pharmacies) may not know when a prescription is an initial fill of a new medication, and this information is not necessarily readily available from the beneficiary or physician, whereas the days' supply is available from the prescription. Therefore, we are revising our requirement such that Medicare Part D sponsors will be required to provide their enrollees access to a daily cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30-days' supply of covered Part D drugs (unless an exception applies due to the type of drug involved) regardless of the reason the prescriptions are so dispensed. This will obviate the need for health plans, PBMs, pharmacies, physicians, and beneficiaries to communicate the reasons for the less-than-30-day supply, and also make it unnecessary to specifically define ''trial fill.'' This revision also takes into account our understanding that pharmacists, under applicable law, can currently dispense a smaller quantity than is written on certain prescriptions at a customer's request, and thus there may occasionally be other reasons for less than a month's supply to be dispensed than the three reasons we identified in the proposed rule. To be clear, the industry can still decide to develop coding in order to best manage these transactions, but none is required by this final rule with comment period.

Comment: A few commenters suggested we adopt a ''copayment by days' supply'' structure with respect to plans that have a copayment structure, whereby Part D enrollees would be charged a set copayment amount based on a range of days dispensed, for example, a $10 copayment for 1–10 days, and a $20 copayment for 11–20 days and so on. These commenters asserted that, for a variety of reasons, this structure would be simpler to implement, including: (1) It would dovetail with the LTC dispensing requirements at § 423.154; (2) it would not require the maintenance of an exception drug list; and (3) it would enable Part D plans to more accurately model and predict drug costs.

Response: We decline to revise our requirement in the manner suggested by the commenters. We do not believe it would necessarily dovetail better with the LTC dispensing requirements than our requirement, as those requirements require the implementation of 14 days' supply *or less* dispensing, and thus under the commenters' suggested approach, copayments in an LTC facility could still vary. In addition, we do not believe our requirement will necessitate an exception drug list, as we discuss later in this section. Finally, we believe that creating additional multiple ''copay tiers'' based on the days' supply dispensed, as suggested, would significantly increase beneficiary confusion in evaluating benefit packages, which already contain copayment tiers based on the type of drug.

Comment: Some commenters stated that Part D sponsor and network pharmacy interests should be aligned in terms of quality of patient care, reduction of waste and the associated savings with our proposal, such that the stakeholders should be able to work together to ensure that certain pharmacies do not game our proposal. Other commenters stated that pharmacies may dispense a prescription in multiple stages, even when it is not so prescribed, to generate additional dispensing fees, and that the net value of any anticipated offsets should include such manipulation.

Response: The proposed rule recognized the possibility of manipulation by network pharmacies to increase dispensing fees, and as noted previously, we urged the industry to develop appropriate coding so that the pharmacies could communicate the reason for dispensing less than a month's supply, even though the reason is not required under our revised, simplified requirement, as described previously. Although we will not mandate such coding, we do not think it would be unreasonable for sponsors to ask pharmacies to attest as to why a prescription was dispensed for less than a month's supply. We would also expect that sponsors will implement contractual terms and auditing and other internal controls to detect and prevent fraud, waste, and abuse and to ensure that pharmacies are not inappropriately splitting prescriptions to increase dispensing fees, and thus costs to beneficiaries and the program. We further note that if pharmacies dispense prescriptions in stages merely in order to increase dispensing fees, they would have to have the cooperation of the affected beneficiaries, and we do not anticipate beneficiaries desiring less than a month's supply of a medication, absent the recommendation of their physicians, to any significant degree, particularly given the potential inconvenience involved. Additionally, engaging in this activity may constitute fraud by the network pharmacy against the Part D sponsors involved and the Federal government, and we would expect sponsors to take action appropriate against such activity, such as terminating the pharmacy from its network. Consequently, we agree with the commenter that stakeholders' interests should be aligned under our requirement, and we do not agree that potential additional dispensing fees would completely or even significantly offset potential savings associated with this requirement.

Comment: A commenter stated that the purpose of cost-sharing obligations is to provide beneficiaries with a financial connection with the health care service they receive, which assists in countering potential overutilization, and implied that reduced cost-sharing would be less effective in this regard.

Response: While we agree that cost-sharing obligations create a financial connection between beneficiaries and the health care services they receive, we disagree that our requirement would engender overutilization. On the contrary, under our requirement as revised, a beneficiary will pay the same cost-sharing for a month's supply of medication dispensed in multiple stages that the beneficiary would otherwise pay.

Comment: Other commenters were concerned that Part D enrollees would be incentivized to obtain a lesser quantity of a medication than written by their physicians at the pharmacy counter in cases where the physician would not want the enrollee to take the medication on a trial basis, which would negatively affect the beneficiary's medication adherence. A commenter acknowledged that plans that utilize coinsurance structures already accommodate the concept of assessing a lower cost share when less than a month's supply is dispensed, and did not indicate that this causes problems with adherence today.

Response: We are unclear what scenario the commenter is envisioning, but we presume it to be that a beneficiary who currently takes a medication will begin to take less because he or she will be able to pay lower cost-sharing for less than a month's supply. We do not believe our requirement would cause more instances of this scenario than currently may be the case. As noted previously, it is our understanding that, if permitted under applicable law, pharmacists currently may dispense a lesser quantity than prescribed at a customer's request, and we are not aware that this possibility negatively affects medication adherence today. In contrast to lower cost-sharing incentivizing beneficiaries to take less medication than they already do, we think lower cost-sharing is just as likely, if not more likely, to incentivize beneficiaries to begin taking medications they have avoided altogether due to cost-sharing.

Comment: A commenter stated that physicians are currently allowed to write prescriptions for a less than a month's supply, and that reducing Part D enrollees' copayments for such prescriptions will not incentivize physicians to do so more frequently.

Response: As noted previously, our requirement is directed at incentivizing beneficiaries, who actually pay the cost-sharing, to consider along with their prescribers, whether a less-than-30-days' supply of a new medication would be appropriate. Indeed, we believe that prescribers are generally unaware of the copayments that their patients pay for prescriptions. To the extent that prescribers are aware of cost-sharing today, we would argue that prescribing patterns are currently influenced by the inflexible cost-sharing arrangements in prescription drug plans today, so it would not make sense for prescribers to write for shorter days' supplies if the industry standard is to charge a whole month's cost-sharing.

Comment: A commenter noted that Part D plans currently have in place member-friendly provisions that permit members to pay the lesser of the copayment amount or the cost of the particular Part D covered drug. Accordingly, if a prescriber were to write a prescription for a less than a month's supply and the total cost were less than the member's copayment, the member would only be responsible for the lesser amount. The commenter asserted such provisions are a more appropriate way to ensure that members receive the benefit of a less than a month's supply option without increasing administrative burden to plans.

Response: We see these policies as complementary, not alternatives. We believe the lesser of copayment or cost will generally result in lower cost-sharing than monthly copayments for relatively less expensive drugs.

Comment: A commenter requested clarification on support in member documents, assuming that Plan Finder, Evidence of Coverage, and Summary of Benefits, would not include detailed information on daily cost-sharing rates, since they are not the norm.

Response: We intend to include language in future Medicare & You and the Part D Evidence of Coverage (EOC) documents on availability of daily cost-sharing rates and on when beneficiaries should consider taking advantage of them. We are currently reviewing the level of detail that we think is appropriate to be included in Summaries of Benefits, as daily cost-sharing rates are optional for the beneficiary under this requirement. At this point, we do not think that Plan Finder needs to add this level of complexity, since its purpose is to help beneficiaries compare costs of their current medications in different plans—not to price shortened days' supplies of new prescriptions.

Comment: A commenter was concerned that the proposal would be very confusing to beneficiaries, and that it is predicated on the belief that prescribers have actual knowledge if patients fill or refill prescriptions, and that there is an opportunity for these parties to have meaningful conversations about a medication's relative cost.

Response: As we noted in the preamble to the proposed rule, the decision to try a medication for less than a month's supply would generally be made by the Medicare Part D enrollee and his or her prescriber, and if an enrollee would have difficulty returning to the pharmacy, or even broaching the subject with his or her prescriber, then we believe he or she would not seek to obtain a smaller supply of a medication.

Comment: Some commenters believed our proposal would result in better adherence, specifically referencing that our proposal would greatly facilitate current efforts by community pharmacists to achieve better adherence through refill synchronization. Other commenters believed that medication adherence would be negatively affected if Part D enrollees did not return to the pharmacy to pick up the next supply of a medication, when it was determined by their prescriber that the medication should be continued after an initial trial fill, for example. A commenter stated that our proposal seems to run counter to using adherence rates as a 5-star metric to measure the quality of a plan's clinical services, and that there is data in the literature that shows patients may not return to the pharmacy to fill the remainder of a prescription under circumstances envisioned by our proposal.

Response: We were persuaded by the comments that our requirement would assist pharmacists in synchronizing Part D medication refill dates. Also, as noted previously, the policy behind our requirement is to incentivize the appropriate elimination of unused medication that our data shows is already present in the Part D program. That is, a certain percentage of initial fills of maintenance medications for chronic conditions are not refilled by enrollees, and this indicates that the medications were not effective, tolerated, or continued, for whatever reason, and therefore presumably, a portion of the initial supply was not used, either. The commenter did not specify the referenced literature, so we are unable to review it, and we would note that, since daily cost-sharing rates are not the current industry standard, we are unclear on what data the literature would be based. We address star ratings later in this section.

Comment: A commenter stated that the prescriber writing two prescriptions is the method generally employed by community pharmacists to assist patients in synchronizing the refill dates of multiple prescriptions and would work for trial fills, as well.

Response: We appreciate the confirmation that this practice is already familiar to many prescribers and pharmacies.

Comment: A commenter disputed that many beneficiaries would be willing to undertake the analysis necessary to synchronize multiple prescriptions and coordinate with their prescribers' offices. Another commenter stated that beneficiaries can currently synchronize multiple medications over months, and that allowing refill-too-soon edits to be overridden could contribute to fraud, waste, and abuse. Another commenter requested additional clarification from CMS in terms of medications that beneficiaries are permitted to synchronize, how many times this may occur per year, what documentation would be needed, and what safeguards plans may implement at point-of-sale to review such claims for fraud, waste, and abuse issues, etc.

Response: Our proposal acknowledged that Part D enrollees could take advantage of daily cost-sharing rates to synchronize multiple prescriptions on a voluntary basis, likely with pharmacists playing a role in assisting them, so we do not believe that our requirement should be modified because some enrollees will not take advantage of it to synchronize their medications. While beneficiaries may be able to synchronize medications currently, they are disincentivized from doing so under current cost-sharing structures that generally assume at least a month's supply will be dispensed. Under our revised, simplified requirement, as described previously, Medicare Part D sponsors will be required to provide their enrollees access to a daily cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days' supply of covered Part D drugs (unless an exception applies due to the type of drug involved), regardless of the reason, unless fraud is suspected. We believe that beginning this requirement on January 1, 2014 will give sponsors sufficient time to appropriately program their systems to account for changes to refill-too-soon and other similar edits. Despite eliminating the requirement to apply a daily cost-sharing rate only in specific circumstances, such as for synchronization, we note that our policy does not prevent sponsors from developing coding requirements or other internal controls to ensure pharmacists are not splitting prescriptions to increase dispensing fees.

Comment: A commenter requested that additional information should be provided on the methodology that will apply when prescribers take advantage of our proposal to synchronize the dispensing dates of multiple medications, as this would impact the Adherence Measure in the Patient Safety Reports because of the different dispensing dates and alterations in days' supply of the medications, and classify a patient as not adherent, which would affect Star Rating Measures.

Response: Comments about the star ratings are outside the scope of this rulemaking, but we do not believe a daily cost sharing rate requirement would have any negative impact on our ability to measure medication adherence because, for example, if a Part D enrollee does not return to the pharmacy for the second fill, he or she will not be captured in the measure calculation (which requires at least two fills of a drug in the classes measured for adherence). Also, we account for multiple fills for the same drug when the days supply overlap.

Comment: A commenter stated that our proposal should not apply to controlled substances because prorating cost-shares is not permitted. More specifically, this commenter stated that multiple prescriptions for the same controlled substance may not be permitted under state law, including post-dating one for future dispense, and that pharmacists cannot change quantities dispensed on prescriptions for controlled substances.

Response: To the extent that applicable Federal and/or State law prohibits two prescriptions from being written simultaneously for the same medication, a prescription from being refilled by a physician directly with the pharmacy, and/or a lesser quantity than was prescribed from being dispensed, our requirement would not supersede such law. Therefore, we have revised the regulation text so that the daily cost-sharing rate requirement applies to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that may be dispensed for a supply less than 30 days under applicable law.

Comment: A commenter supported application of our proposal to LTC dispensing, asserting it would create consistency in the claims and billing processes, which could otherwise be chaotic if inconsistent approaches are adopted by Part D sponsors. Another commenter was opposed, stating strong concerns that LTC pharmacies would have to expend considerable staff time and cost creating paper invoices for extremely nominal amounts and collecting LIS fees, many of which go uncollected anyway.

Response: As noted previously, based on comments received, this requirement will not begin until January 1, 2014. However, Part D sponsors can voluntarily choose to apply a daily cost-sharing rate in the LTC setting in 2013 or not, or for that matter, in the retail setting or not. Beginning January 1, 2014, under our revised, simplified requirement, as described previously, Medicare Part D sponsors will be required to provide their enrollees with access to a daily cost-sharing rate when the covered Part D drug may be dispensed by a network pharmacy for less than a 30 days' supply (unless an exception applies due to the type of drug involved), regardless of the reason, unless fraud is suspected. Thus, there is no longer any reference to the LTC dispensing requirements in the regulation text. We note that, because Part D sponsors must offer a uniform benefit, we are unable to exempt Part D enrollees residing in LTC facilities from the requirement. Moreover, we agree with the commenter who stated that a consistent approach among Part D sponsors in the LTC setting with respect to cost-sharing is ideal and note that our requirement does not address when daily cost-sharing amounts would have to be collected from LTC beneficiaries. Thus, LTC pharmacies and facilities may implement consolidated monthly cost-sharing collection irrespective of the cost-sharing methodology assessed on claims. We also note that the majority of Part D enrollees in LTC have no copays.

Comment: A commenter stated that LTC customers routinely request synchronization of patient medications for their residents and asked that we clarify that the ability to synchronize refills is available to LTC customers.

Response: Under our revised, simplified requirement, as described previously, the ability to synchronize refills will be available in LTC settings.

Comment: A commenter expressed support for LIS beneficiaries to continue making nominal copayments for prescriptions filled for less than a month and recommended that we consider capping total cost-sharing amounts for such beneficiaries who take multiple medications, since the combined cost of daily-cost-sharing could jeopardize the ability to comply with such prescription drugs regimens.

Response: Under our requirement, LIS enrollees would not pay any more in cost-sharing for a month's supply of medication than they would otherwise. However, we are revising our proposed definition of ''daily cost-sharing rate'' to make this clearer, as indicated by the underlining later in this final rule with comment period. Thus, with respect to copayments, ''daily cost-sharing rate'' is defined as ''the established monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, *if any,* or to another amount, but in no event to an amount *which would require the enrollee to pay more for a month's supply of the prescription* than would otherwise be the case.'' We have added the ''if any'' language specifically in recognition that some daily cost-sharing rates may be below $1. We do not have authority under the statute to cap aggregate LIS cost-sharing, except as provided after the out-of-pocket threshold has been met.

Comment: Some commenters expressed concern about the effect of our proposal on the already very low cost-sharing payments of some Part D enrollees. Commenters noted that, because many plans have cost-sharing on the preferred generic tier that is lower than the LIS brand cost-sharing, our proposal would cause the copayments of enrollees other than just LIS enrollees to be nominal, particularly with respect to generic medications, and with respect to some dual-eligibles, and the copayments might even round down to $0, depending upon on the days supply prescribed by the prescriber. Several commenters asserted that generics should be exempted from our proposal due to their low-cost-sharing and the cost associated with dispensing them. A commenter offered an alternate proposal for LIS enrollees, which was to require Part D sponsors to offer a 15 days' supply for half the normal copayment since dividing their already nominal copayments by 30 days could be impractical.

Response: While we recognize that generics are generally associated with low cost-sharing, not all generics may be, and we believe our requirement should apply to all medications (unless an exception applies due to the type of drug involved). Moreover, the MaineCare program cited previously achieved savings even with the inclusion of generic drugs. We also remind stakeholders that our requirement applies to Part D sponsors, but beneficiaries are not required to avail themselves of this option. Therefore, if beneficiaries are not sufficiently incentivized by the lowered cost-sharing applicable to a less-than-month's supply of medication, they presumably will not ask their prescribers to write a prescription for less than a month's supply or their pharmacists to dispense one. Even if beneficiaries do ask in some instances, the volume of unused drugs that must be discarded will be reduced, even if the costs are not less. Nevertheless, we expect this requirement, even as revised, to be most attractive to enrollees when their drugs are relatively more expensive and for maintenance medications for chronic conditions. We do not believe that that these nominal cost-sharing scenarios would occur very often. However, recognizing that this requirement may result in nominal cost-sharing amounts for a less than month's supply, or none, if Part D sponsors choose to round the applicable copayment down to $0, we have added, ''if any'' after ''rounded to the nearest lower dollar amount,'' in the definition of ''daily cost-sharing rate.'' This change recognizes that, in the case of LIS enrollees, or other enrollees for that matter, there will not be a ''lower dollar amount'' when making the calculation required by the definition if the ''established monthly copayment'' is lower than the $30 to $31 range.

Comment: A commenter stated that if a plan's preferred generic cost share is $2, the pro-rated cost share would be $.46 for a 7 days' supply of the medication, which would be rounded up to $1, so the enrollee would be paying half the regular cost-share for a 1 week supply.

Response: The commenter is not correct. Under our proposed definition of ''daily cost-sharing rate,'' as applied to a monthly copayment, $2 would be divided by 30 (or 31) and then rounded to the nearest *lower* dollar amount ($0), or to another amount (for example, $0.06), but in no event to an amount which would require the enrollee to pay more for a month's supply than would otherwise be the case. In other words, the Part D sponsor can alternatively choose to round to $0.06 or $0, since another figure, for instance $0.07, is a daily cost-sharing rate (or any higher amount) that, when applied to a 30 days' supply, would cause the enrollee to pay $2.10 (or more) for a 30 days' supply, which is not permitted under the proposed definition. Thus, the copayment for a 7-day supply in this example (based on 30 days being a month's supply) would be $0.42 or $0. We note that this definition also does not allow for rounding to the higher dollar amount, as was done in the example given by the commenter. However, for further clarity, we have further revised the regulation text to add the word ''lower.''

Comment: Some commenters requested that we provide more rounding guidance.

Response: We will consider addressing rounding in more detail in guidance, and we will consider suggestions from the industry as appropriate in the development of any such guidance.

Comment: A commenter stated that including the coinsurance calculation in the definition of ''daily cost-sharing rate'' is incorrect and unnecessary, because a coinsurance percentage already applies to the allowed amount (for example, sum of ingredient cost, dispensing fee, vaccine administration fee, and sales tax). A commenter requested clarification that for drug tiers using coinsurance, the proposal would result in no change in the coinsurance percentage as enrollee cost-sharing would simply be determined via mathematics, as well as our expectations on ''daily cost-sharing rates'' for plan designs that include coinsurance with a minimum, maximum, or both.

Response: We agree and have revised § 423.100 and § 423.153(b) accordingly so that, with respect to coinsurance, ''daily cost-sharing rate'' is defined as the established coinsurance percentage under the enrollee's Part D plan, and so that it is not multiplied by the days supply actually dispensed. We also confirm that coinsurance percentages would not change under our requirement, nor would minimum or maximum coinsurance amounts be affected, if applicable to an enrollee's Part D plan.

Comment: A commenter asked for clarification on whether 30 or 90 days should be used to calculate the daily cost-sharing rate for copayments for Part D LIS enrollees.

Response: Since a month's supply is typically a 30 to 31 days' supply, the proposed definition of ''daily cost-sharing rate'' is based on a month's supply which consists of 30 or 31 days, regardless of whether the enrollee is an LIS enrollee or not.

Comment: Several sponsors asked how dispensing fees would be prorated.

Response: If the dispensing fee is included in the copayment, it will be ''prorated'' by virtue of the copayment being divided under the calculation in § 423.100 (definition of daily cost-sharing rate) to establish a daily cost-sharing rate in case of a copayment. With respect to coinsurance, § 423.100 defines the daily cost-sharing rate as the established coinsurance percentage under the enrollee's Part D plan. Thus, to the extent that the established coinsurance percentage is applied to the dispensing fee, the beneficiary will be liable for the specified coinsurance percentage of the dispensing fee for each fill. *Therefore,* beneficiaries may have a higher liability under a shorter fill for a given month if the beneficiary has to pay his/her share of a dispensing fee multiple times under a coinsurance arrangement.

Comment: Several commenters asked how they should account for daily-cost sharing in their annual bids.

Response: We believe that Part D sponsors have the requisite actuarial expertise to adequately estimate the potential effects on utilization and costs generated by our requirement for their annual bids. Previously, we stated that our savings assumptions were highly uncertain, because it is very difficult to predict beneficiaries' behavioral response. However, we were able to estimate savings based on our data on first fills for chronic medications that are not refilled, removing costs associated with the LTC setting, and then making some assumptions about beneficiaries' response to the daily cost-sharing rate requirement, while accounting for additional dispensing fees, which we described previously. We believe sponsors' actuaries will undertake a similar analysis to account for the daily cost-sharing rate requirements in Part D plan bids.

Comment: A few commenters requested that a list of drugs excepted from the daily cost-sharing rate requirement be provided by CMS or claims processors.

Response: As we noted previously, we do not believe our requirement will cause the need for an exception drug list. The daily cost-sharing rate requirement would apply to solid oral doses of drugs that may be dispensed for a supply less than 30 days under applicable law, except antibiotics or drugs which are dispensed in their original containers as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, steroid dose packs). However, unlike the long-term care dispensing requirements which apply only to brand drugs, we are proposing here that the daily cost-sharing rate requirement would apply to both brand and generic drugs. We believe the industry has the expertise to administer this policy without our assistance.

Comment: A commenter stated that certain drug therapies in solid oral dosage forms are inappropriate for dispensing in less than 30 days' supplies, because they take longer to be effective.

Response: We believe prescribers will know when writing for a limited days supply is appropriate and will not do so when not clinically appropriate.

After consideration of the public comments received, we are finalizing our daily cost-sharing rate proposal with the following modifications previously noted. Therefore, we have revised the definition of ''daily cost-sharing rate'' in § 423.100. ''Daily cost-sharing rate'' means, as applicable, the established—(1) monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case; or (2) coinsurance percentage under the enrollee's Part D.

In addition, we will revise § 423.104 by adding a paragraph (i) to state that a Part D sponsor is required to provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4). Section 423.153(b) currently requires a Part D sponsor to establish a reasonable and appropriate drug utilization management program. We will revise § 423.153(b) by adding a new paragraph (4). Paragraph (4)(i) will require a drug utilization management program to establish and apply a daily cost-sharing rate to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply of less than 30 days, and in the case of a monthly copayment, multiplied by the days supply actually dispensed. Paragraph (b)(4)(i)(A) would limit the requirement to drugs that are in the form of solid oral doses and may be dispensed for a supply less than 30 days under applicable law. Paragraph (b)(4)(i)(B) would state that the requirements of (b)(4)(i) would not apply to antibiotics or drugs dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

E. Clarifying Program Requirements

We have worked with MA organizations and Part D sponsors to implement the Medicare Advantage and Prescription Drug Benefit Programs since the inception of these programs. As part of this partnership, we have implemented operational and/or policy guidance via HPMS memoranda or manuals instruction to assist MA organizations and Part D sponsors in ensuring the proper and efficient administration of the Part C and D programs. In this section, we are finalizing provisions that codify some of that guidance and provide other definitive direction on policy issues in order to address requests from stakeholders. These proposals appear in Table 6.

TABLE 6—PROVISIONS TO CLARIFY PROGRAM REQUIREMENTS

Preamble Section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.E.1	Technical Corrections to Enrollment Provisions.	Subpart K	417.422 417.432	Subpart B	422.60	Subpart B	423.56
II.E.2	Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans.	Subpart K	417.427	N/A	N/A	N/A	N/A
II.E.3	Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement.	N/A	N/A	Subpart C	422.101	N/A	N/A
II.E.4	Technical Change to Private Fee-For-Service Plan Explanation of Benefits Requirements.	N/A	N/A	Subpart E	422.216	N/A	N/A
II.E.5	Application Requirements for Special Needs Plans.	N/A	N/A	Subpart K Subpart N	422.500 422.501 422.502 422.641 422.660	N/A	N/A
II.E.6	Timeline for Resubmitting Previously Denied MA Applications.	N/A	N/A	Subpart K	422.501	N/A	N/A
II.E.7	Clarification of Contract Requirements for First Tier and Downstream Entities.	N/A	N/A	Subpart K	422.504	Subpart K	423.505
II.E.8	Valid Prescriptions.	N/A	N/A	N/A	N/A	Subpart C	423.100 423.104
II.E.9	Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings.	N/A	N/A	N/A	N/A	Subpart D	423.153
II.E.10	Employer Group Waiver Plans Requirement to Follow All Part D Rules Not Explicitly Waived.	N/A	N/A	N/A	N/A	Subpart J	423.458
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers.	N/A	N/A	N/A	N/A	Subpart C	423.120

1. Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)

In our October 11, 2011 proposed rule we proposed a number of technical corrections to our enrollment regulations (76 FR 63056). Specifically we proposed the following changes:

• At § 417.422(d) (Eligibility to enroll in an HMO or CMP) and § 417.432(d) (Conversion of enrollment) we proposed to remove references to signatures thereby ensuring that all of our regulations conform with allowing cost plans to utilize alternate enrollment mechanisms.

• At § 422.60(c) (Election process) we proposed to revise an outdated cross-reference.

• At § 423.56 (Procedures to determine and document creditable status of prescription drug coverage) we proposed to remove an outdated reference to the Annual Coordinated Election Period.

We received no comments on these proposals, and therefore, are finalizing this provision without modification.

2. Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans (§ 417.427)

In our April 2010 final rule (75 FR 19783 through 19785), we exercised our authority under sections 1876(c)(3)(C) and 1876(i)(3)(D) of the Act to extend the MA marketing requirements to section 1876 cost contract plans. Under section 1876(c)(3)(C) of the Act, we may regulate marketing of plans authorized under section 1876 of the Act to ensure that marketing material is not misleading. Section 1876(i)(3)(D) of the

Act gives the Secretary the authority to impose ''other terms and conditions'' under contracts authorized by the statute that the Secretary finds ''necessary and appropriate.'' As a result, since contract year 2010, cost plan contractors have been required to follow all marketing requirements specified in Subpart V of Part 422, with the exception of § 422.2276, which permits an MA organization to develop marketing and informational materials specifically tailored to members of an employer group who are eligible for employer-sponsor benefits through the MA organization, and waives requirements to review such materials. In our April 2010 final rule (75 FR 19785), in which we discuss extending MA marketing requirements to cost contracts, we note that the statutory authority under section 1857(i)(1) of the Act, which permits the Secretary to waive certain requirements for employer group plans under the MA program, does not apply to cost plans.

In extending the marketing requirements to cost contract plans in our April 2010 final rule, we neglected to extend the MA organization and Part D sponsor disclosure requirements, at § 422.111 and § 423.128, respectively, to cost contract plans. As we specified in the proposed rule, we believe that extending these provisions would also be appropriate, given the close relationship between the marketing requirements in Subpart V of Parts 422 and 423 and the disclosure requirements at § 422.111 and § 423.128. These provisions require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. They also require the provision of certain information and establish requirements with respect to: (1) The explanations of benefits notice, (2) customer service call centers, and (3) Internet Web sites. Thus, these requirements are closely tied to the marketing requirements of Subpart V of Parts 422 and 423. In order to ensure that cost contract plan enrollees have all the information they need about their health care benefits, we believe that cost contract plans should also be subject to all the same disclosure requirements as MA organizations and Part D sponsors. Therefore, we proposed to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans by adding a new § 417.427.

Comment: A commenter supported the provision as specified in the proposed rule.

Response: We thank the commenter for its support.

Comment: A few commenters believe the effective date of 60 days after publication of the final rule does not allow enough time for Medicare cost contract plans to implement the new requirements and that the requirements instead should become effective no sooner than for the 2013 annual election period (that is, in the Fall of 2012).

Response: Although the provisions of the rule are effective 60 days after publication of the rule, the disclosure requirements are primarily carried out through the ANOC/EOC, so we would indeed expect that the disclosure requirements would be implemented during the 2013 annual election period (Fall of 2012), the first such period after the effective date of the regulations.

Comment: A commenter stated that changing the ANOC/EOC delivery date from December 1 to 15 days prior to the beginning of the annual election period would not be appropriate for cost contract plans that include only Medicare benefits, (that is, no supplemental benefits). The commenter stated that CMS may not have released the applicable deductible amounts for the following contract year at the time the ANOC is required to be distributed, which is a significant issue because some cost plans mirror Original Medicare cost-sharing amounts.

Response: We will continue to require that cost plans not offering Part D send the ANOC for member receipt by December 1. It was not our intention to change this date for cost plans. We will clarify this in forthcoming plan guidance. All cost plans offering Part D must currently follow the MA ANOC timelines, and must send the ANOC for member receipt 15 days before the beginning of annual coordinated election period.

Comment: A commenter notes that, contrary to the MA disclosure language at § 422.111(b)(7), which states that non-contract providers submit claims to the MA organization, non-contract providers would submit claims to the Medicare administrative contractor (MAC), not the cost contract plan. The commenter asks that we address this issue in the regulation by establishing a waiver process for MA provisions that do not apply to cost contract plans.

Response: We will clarify in the cost contract plan EOC that, in most instances, non-contract providers should submit claims to the MAC, and not directly to the cost contract plan. Therefore, we do not believe that it is necessary to establish a general exceptions process to waive MA requirements.

After consideration of the public comments received, we are finalizing the policy without modification.

3. Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement (§ 422.101)

Section 1858(b) of the Act provides that, to the extent RPPO plans use a deductible, any such deductible must be a single deductible, rather than separate deductibles for Parts A and Part B benefits. This single deductible may be applied differentially for in-network services and may be waived for preventive or other items and services. Our regulations at § 422.101(d)(1) track the language in the statute closely. They require that RPPO plans, to the extent they apply a deductible, apply only a single deductible related to combined Medicare Part A and Part B services. They also allow the single deductible to apply only to specific in-network services and to be waived for preventive services or other items and services, at the plan's option. However, both the statute and our regulations are silent with respect to any deductible requirements for local preferred provider organization (LPPO) plans. Consequently, in practice, LPPO plans may have a variety of deductible designs, including separate in-network and out-of-network deductibles.

We proposed to make three changes to our regulations at § 422.101(d)(1) to both clarify current requirements with respect to the application of a single deductible and to level the playing field between LPPO and RPPO plans by extending the RPPO rules to LPPOs. Specifically, we proposed to clarify the application of the single deductible differential for in-network services and modify our current regulations to take into account recent rulemaking under which MA plans must provide certain Medicare-covered preventive services at zero cost sharing. We proposed to rely upon our authority at section 1856(b)(1) of the Act to establish MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional terms and conditions, found necessary and appropriate, to extend the RPPO single deductible requirements by regulation to LPPOs. We believe that having the same rules for LPPOs and RPPOs supports transparency and comparability of options for beneficiaries when they evaluate and select plans for enrollment. In previous rulemaking, we took steps to align the plan design requirements for RPPOs and LPPOs. For example, in our April 2010 final rule (76 FR 21507 through 21508) that made revisions to the MA and Part D programs for CY 2012, we extended the same maximum out-of-pocket (MOOP) and catastrophic limits we had previously codified for LPPOs (75 FR 19709 through 19711) to RPPOs. In the interest of transparency, alignment in benefit design between RPPO and LPPO plans, and comparability for beneficiaries making health care coverage elections, we proposed to extend to LPPOs the single deductible requirements at § 422.101(d)(1). We would clarify the rules that would now apply to both LPPO and RPPO plans as set forth later in this section.

As discussed previously, we proposed to clarify at § 422.101(d)(1) that an LPPO or RPPO single deductible ''may be applied differentially for in-network services,'' as provided under section 1858(b) of the Act. We currently furnish interpretive guidance and examples of the application of the single deductible in section 50.3 of Chapter 4 of the Medicare Managed Care Manual, ''Benefits and Beneficiary Protections'' *http://www.cms.gov/manuals/downloads/mc86c04.pdf*). However, we believe there may still be confusion with respect to how these requirements are articulated in our regulations and therefore proposed amending § 422.101(d)(1) to add paragraphs (i) through (iii) clarifying that an RPPO or LPPO that chooses to apply a deductible may both—

• Specify different deductibles for particular in-network Parts A and B services, provided that all of these service-specific deductibles are applied to the overall, single plan deductible; and

• Choose to exempt, that is, exclude, specific plan-covered items or services from the deductible. That is, the LPPO or RPPO may choose to always cover specific items or services at plan-established cost-sharing levels regardless of whether the deductible has been met. For example, under our regulations, an LPPO or RPPO could establish a single combined deductible of $1,000 but limit the amount of the deductible that applies to in-network inpatient hospital services to $500, and the amount that applies to in-network physician services to $100. This LPPO or RPPO could also choose to exclude particular in-network services from application of the deductible altogether; for example, all in-network home health services would not be subject to the deductible.

In our April 2011 final rule (76 FR 21475 and 21476), we established a new requirement for MA organizations to provide certain in-network Medicare-covered preventive benefits at zero cost sharing. As provided under § 422.100(k), MA organizations, including those offering PPO plans, may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services specified in § 410.152(l). Therefore, we will now require both LPPO and RPPO plans to exclude preventive services from the single deductible at § 422.101(d)(1), and will add a new paragraph § 422.101(d)(1)(iv) that explicitly requires LPPO and RPPO plans to exclude certain Medicare-covered preventive services (as defined in § 410.152(l)) from the single, combined deductible.

Comment: A commenter supported CMS' proposed clarification of the rules for RPPO plans with a deductible.

Response: We thank the commenter for its support.

After consideration of the public comment received, we are finalizing the proposed clarifications of the RPPO deductible and extension of deductible rules to local PPO plans without modification.

4. Technical Change to Private Fee-for-Service Plan Explanation of Benefits Requirements (§ 422.216)

In our April 15, 2011 final rule (76 FR 21504 through 21507) implementing changes to the MA and Medicare Prescription Drug Programs for Contract Year 2012, we finalized regulations at § 422.111(b)(12) giving us the authority to require MA organizations to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part. We expressed our intention to work with MA organizations, Part D sponsors, and beneficiary advocates to develop an Explanation of Benefits (EOB) for Part C benefits and to test the EOB in CY 2012 through a small, voluntary pilot program. In our April 2011 final rule (76 FR 21505), we also stated our intention to finalize a model EOB in the future, based on the results of the pilot program and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits.

We did not specifically discuss private fee-for-service (PFFS) plans in our April 2010 final rule because section 1852(k)(2)(c) of the Act and § 422.216(d)(1) already require PFFS plans to provide an EOB to enrollees. Our current regulations at § 422.216(d)(1) specify that PFFS plans must provide an appropriate EOB to plan enrollees for each claim filed by the enrollee or the provider that furnished the service. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing. In the interest of consistency for beneficiaries and MA organizations, we proposed—in our October proposed rule—to amend § 422.216(d)(1) to state that the EOB requirement for PFFS plans will be consistent with the MA EOB requirements of § 422.111(b)(12). The standard EOB that we are currently developing and piloting for most of the other MA plan types will include the same information as currently required for PFFS plans, as well as plan maximum out-of-pocket (MOOP) cost information. Adding this cross-reference to § 422.216(d)(1) would provide consistency in EOB requirements as well as submission and approval of marketing materials across plan types. Since the pilot program is in progress during the CY 2013 rule development cycle and we would not have finalized EOB requirements based on the pilot prior to publication of the CY 2013 final rule, we proposed that PFFS plans would continue to furnish EOBs as they have been, in accordance with § 422.216(d)(1), until we finalize and implement EOB models for all MA plans.

We did not receive any comments on this provision in the proposed rule; therefore, we are finalizing this technical change as proposed.

5. Application Requirements for Special Needs Plans (§ 422.500, § 422.501, § 422.502, § 422.641, and § 422.660)

Section 1859(f) of the Act and its implementing regulations specify several requirements for Special Needs Plans (SNPs). MA organizations that would like to offer a SNP are required to engage in an intensive application process to demonstrate that they meet these SNP specific requirements, including the requirement in § 422.101(f) that MA organizations offering a SNP implement an evidence based model of care (MOC) to be evaluated by NCQA; the requirement in § 422.107 that Dual Eligible SNPs (D–SNPs) have a contract with the State Medicaid Agencies in the States in which they operate; and the requirement in § 422.152(g) that SNPs conduct a quality improvement program. SNP applicants follow the same process in accordance with the same timeline as applicants seeking to contract as MA organizations.

Accordingly, we proposed to broaden the regulations on Medicare Advantage (MA) Application Requirements and Evaluation and Determination Procedures, in accordance with section 1859(f) of the Act, to apply to SNP applicants. Specifically, we proposed to revise the language in § 422.500(a) and § 422.501(a) to specify that the scope of these provisions include the specific application requirements for SNPs. We also proposed to add paragraph (iii) to § 422.501(c)(1) to specify the documentation SNP applicants must provide to complete an application. Furthermore, we proposed to revise § 422.502(a) and § 422.502(c) to specify that our regulations on application evaluations and determinations apply to SNP applications.

Additionally, in accordance with section 1859(f) of the Act, we proposed to provide explicit appeal rights to each applicant that has been determined unqualified to offer a SNP for failure to meet the requirements in section 1859(f) of the Act and its implementing regulations. To do so, we proposed adding a new paragraph (d) to § 422.641, a new paragraph (a)(5) to § 422.660, and a new paragraph (b)(5) to § 422.660. We believe these proposed changes will ensure that only MA organizations capable of meeting the requirements to serve Special Needs Individuals are able to target their enrollment to this vulnerable population, while also affording each MA organization that has been determined unqualified to offer a SNP the opportunity to have this decision reviewed by an impartial hearing officer.

Comment: Commenters expressed their support for our proposals to ensure that SNP applicants have the same rights and responsibilities as other MA contract applicants. A commenter specifically noted its support for consistent rules for all MA options.

Response: We appreciate the commenters' support for this provision, which makes the rules and appeal rights for SNP applicants consistent with the rules governing the MA contract application and appeals process.

Comment: A commenter recommended that we add language to our application regulations to ensure that an entity that has applied as a SNP is presumed to have applied as an MA plan. The commenter thought that such language would be necessary so that the MA organization could operate an MA plan in the event that the MA organization is not able to meet the SNP application requirements necessary to operate a SNP.

Response: It has been CMS' longstanding policy that, in order to offer a SNP, an MA organization must also apply and be approved to offer an MA Coordinated Care Plan (CCP) in the service area in which it would like to offer a SNP. (Please note that a prior year's MA application approval is sufficient to meet this requirement. The plan is not required to submit a new MA application if it has been previously approved to offer a CCP in the service area in which it is applying to offer a SNP.) Accordingly, if an approved MA organization's SNP application is denied, the plan is nonetheless still authorized to bid to offer an MA plan for the upcoming contract year. If an MA organization is applying to offer an MA CCP that is also a SNP, and the SNP application is denied, the MA organization's MA application must still be approved. As such, the language requested by the commenter will not be added to the regulatory text and we will finalize the policy without modification.

Comment: A commenter requested that we modify our substantive regulations on the SNP MOC approvals to specify that SNPs can be approved for multiple years. Another commenter encouraged CMS to provide States with operational support and regulatory guidance regarding the D–SNP State contract requirements.

Response: While we appreciate these suggestions, the MOC approval regulations and D–SNP State contract requirements are outside the scope of this regulation. We will consider these suggestions as we develop future rulemakings and guidance.

After review of the public comments, we are finalizing our proposal without modification.

6. Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)

Section 1857(a) of the Act requires organizations that wish to participate in the MA program enter into a contract with the Secretary under which the organization agrees to comply with all applicable MA program requirements and standards. In order for us to determine whether these program requirements and standards have been met, the organization must complete an application in the manner described at Subpart K of part 422. Section 422.501 sets forth the required elements of such an application. Under § 422.501(e), entities that are seeking to contract with the Secretary as an MA organization may not resubmit an application that has been denied by CMS for 4 months following CMS' denial. This 4-month prohibition on resubmitting a previously-denied application is obsolete and inconsistent with current agency practices, as we presently operate on an annual application cycle. In order to align § 422.501 with current procedures, we proposed revising paragraph (e) to clarify that every organization seeking to become an MA organization must wait until the application cycle for the following contract year to resubmit an application that was previously denied in the current contract year's application cycle.

Comment: A commenter recommended that if a SNP application is denied, the plan should be presumed to have applied for an MA plan; thus, if the application meets MA requirements, the plan will not have to reapply as such.

Response: We have addressed the commenter's concern that a SNP application shall be presumed to be an MA application and approvable if it meets the MA requirements in the comment and response for our provision on applications for SNPs in section II.E.5. of this final rule with comment period.

Comment: The commenter also expressed its support for extending appeal rights to denied SNP applications.

Response: SNP application requirements and appeal rights are outside the scope of this provision.

After consideration of the public comments received, we are finalizing the policy without modification.

7. Clarification of Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)

The regulations at § 422.504(i) and § 423.505(i) require MA organizations and Part D sponsors to require all of the first tier, downstream, and related entities to which they have delegated the performance of certain Part C or D functions to agree to certain obligations. In particular, the regulations require sponsors to have "contracts or written arrangements" that provide, for example: (1) For the delegated entity to carry out its contract in a manner consistent with the sponsor's Medicare contract obligations; (2) that the sponsor may revoke the contract if the sponsor determines that the delegated entity has not performed satisfactorily; and (3) that the sponsor on an ongoing basis monitors the performance of the delegated entity. We believed it was clear that the language of § 422.504(i) and § 423.505(i) required that all contracts governing the relationships among a sponsor and all of its delegated entities (that is, those between the sponsor and its first tier entity; those between the first tier entity and any downstream entity; and those between downstream entities) contain provisions specifically addressing each of the required elements stated in the respective paragraphs. That is, each contract was required to contain ''flow down'' clauses through which each delegated entity would become legally obligated to honor the provisions of § 422.504(i) and § 423.505(i).

In the solicitations for applications for qualification of MA organizations and Part D sponsors, we instructed applicants that all contracts with delegated entities provided for our review must include language addressing all of the elements stated in § 422.504(i) and § 423.505(i). We took this position because: (1) We believed that the requirement was clearly stated in the regulation; and (2) as the sponsor cannot enforce a contract to which it is not a party (that is, it has no privity of contract with its downstream entities), the only way to give the provisions of § 422.504(i) and § 423.505(i) full effect is to require that each subcontract specifically describe the delegated entity's obligations to the sponsor.

This interpretation was challenged in 2010 by an organization whose Part D sponsor qualification application was denied when we determined, among other things, that the contract between the applicant's first tier and downstream entities incorrectly made reference to the rights of the first tier entity, rather than the applicant, in the contract sections the applicant intended to meet the requirements of § 423.505(i). While the hearing officer upheld CMS' denial of the application, in the interest of providing transparency and clarity for the healthcare industry, we have decided to amend the regulation. The changes to the regulation will help future applicants avoid confusion about the requirements related to contracts with first tier and downstream entities, thus helping to streamline the application process.

We believe that the most legally effective and direct way to ensure that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities is by requiring all contracts among those entities to specifically reference each party's obligations to the sponsor, as enumerated in § 422.504(i) and § 423.505(i). Documents or ''written arrangements'' other than contracts can be ambiguous as to the nature of an obligation and who has agreed to perform it. They are unreliable tools for the protection of the rights of sponsors with respect to the performance of their Medicare obligations by their delegated entities. Assurances from delegated entities that they will provide necessary instructions to other downstream entities should the need arise are equally ineffective as they provide no evidence that the downstream entity could be compelled to follow such instructions. Therefore, we proposed to make explicit that sponsors can fulfill the requirements of § 422.504(i) and § 423.505(i) only by providing evidence that the contract of every first tier or downstream entity contains provisions stating clearly that the parties have agreed to recognize and give effect to the sponsor's rights as listed in those subsections. Accordingly, we proposed to delete the term ''written arrangements'' throughout § 422.504(i) and § 423.505(i) and in each instance replace it with ''each and every contract.''

Comment: An MA organization expressed its concern about the use of the term ''contract'' throughout the proposed regulatory change. The organization noted that the term was too narrow and appeared to exclude less formal arrangements that sponsors use to meet their Part C and D obligations. For example, some organizations use related parties (for example, another subsidiary of their parent organization) to perform delegated functions and those relationships may be governed by something other than a contract.

Response: We believe that the term ''contract'' best expresses the nature of the arrangements sponsors must have in place to meet the requirements of § 422.504(i) and § 423.505(i). Therefore, we are retaining the proposed language in the final rule. Nonetheless, we acknowledge that organizations may meet the requirements through the use of documents that may not be expressly labeled as ''contracts.'' These may include letters of agreement or intercompany agreements. Sponsors must simply make certain that the documents they use to memorialize the functions delegated to their first tier, downstream, or related entities contain language that clearly describes an enforceable set of plan sponsor rights and subcontractor obligations to the sponsor, regardless of whether the sponsor is a party to the agreement.

Comment: An MA organization asked that CMS provide more information about the deficiency that led to the application denial discussed in the proposed rule.

Response: More discussion of the facts of the application denial appeal is provided in the CMS Hearing Officer's opinion, *In the Matter of Stonebridge Life Insurance Company, Inc., Denial of Application, S3502,* Docket No. 2010 C/D App. 7. The opinion is posted on the CMS Web site at *https://www.cms.gov/Medicare-Advantage-Prescription-Drug-Plan-Decisions/downloads/2010_CD_App_7.pdf.*

Comment: A commenter requested that CMS clarify that sponsors are not required to directly monitor the performance of all downstream entities to which they have delegated functions but with which they do not directly contract.

Response: The commenter is technically correct that the regulations only require that the contracts that govern the delegated functions among the sponsor's first tier, downstream, and related entities contain provisions expressly granting the sponsor the authority to perform oversight of the activities of the subcontractors. The regulations do not require the sponsor to exercise that authority. That said, we remind sponsors that the Part C and D regulations require them to adopt and implement an effective compliance program which provides for, among other things, the sponsor to establish an effective system for monitoring and auditing its first tier and downstream entities to ensure their compliance with our requirements. We encourages all sponsors to review their compliance program activities to make certain that their methods for oversight of their subcontractors are effective in holding them accountable for Part C and D functions performed on the sponsors' behalf.

Comment: A commenter requested that CMS provide model contracting language that meets the subcontracting requirements discussed in the proposed provision.

Response: The arrangements between a plan sponsor and its first tier, downstream and related entities are subject to considerable variation from sponsor to sponsor. Accordingly, the contracts governing the arrangements must be tailored to reflect their particular features. For example, some arrangements may require a unique contract where the plan sponsor is specifically named in the document while others can be served through a contract template used by a subcontractor that serves multiple plan sponsors and the sponsors are identified by proper reference to another document. We believe that it would be, at best, not useful for CMS to provide model language and at worst, counterproductive as it could create the temptation for sponsors to use the model language in their contracts when a specially-tailored set of terms is needed to properly govern their unique arrangements and to meet the Part C and D program requirements.

Comment: A commenter requested that CMS require MA organizations to provide to their first tier and downstream entities a copy of the organization's Part C contract with CMS. The commenter stated that such a requirement would be useful to subcontractors perform their delegated functions in a manner consistent with the MA organization's contract with CMS.

Response: The subject of this comment is technically outside the scope of our proposal. However, we note that our contracts with Part C and D sponsors consist of uniform terms and conditions for each type of plan offering. Therefore, we have already responded to this request by posting on our Web site all of the current Part C and D contract templates. Subcontractors can now obtain the Medicare plan sponsor contact terms and conditions directly from CMS.

After consideration of the public comments received, we are finalizing the policy without modification.

8. Valid Prescriptions (§ 423.100 and § 423.104)

Since the inception of the Part D program, we have consistently maintained that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law. Using our authority in section 1860D–12(b)(3)(D), we proposed in our October NPRM to codify this policy to remove any doubt as to the appropriate source of law to consult when determining whether a prescription is valid.

We proposed, first, to add a definition of the term ''valid prescription'' to § 423.100 to mean a ''prescription that complies with all applicable State law requirements constituting a valid prescription.'' This would make clear the need to consult State law to determine whether a prescription is valid.

We underscore, as we did in the proposed rule, that we do not intend to impose any State law requirements that do not otherwise apply. Rather, our proposal is that prescriptions must comply with applicable State law requirements; there is no need to comply with State law requirements to the extent that they do not apply. The two following examples illustrate our intent. Some States require that insulin syringes be dispensed upon prescription only, while other States do not. We would not require prescriptions for coverage of insulin syringes under Part D in those States that do not mandate prescriptions, but would require prescriptions for Part D coverage in States that require insulin be dispensed only upon prescription. The second example involves the Indian Health Care Improvement Act (IHCIA), which: (1) Provides that licensed health professionals employed by a tribal health program need not be licensed in the State in which the program performs services; and (2) exempts specified health facilities from obtaining State licenses provided they otherwise meet State law requirements. The proposed changes would not necessitate either that these licensed professionals obtain additional State licenses or that the specified facilities obtain initial State licenses.

We also proposed to add a new paragraph (h) to § 423.104 stating that, for every Part D drug that requires a prescription, Part D sponsors may only provide benefits when that drug is ''dispensed upon a valid prescription''. In tandem with the proposed definition of the term valid prescription discussed previously, these changes would ensure that, for drugs and other items that must be prescribed (including biological products and some insulin and specified associated supplies), Part D coverage would be limited to those dispensed upon valid prescriptions under applicable State law.

At this time, we are not aware of any State that requires that each electronic or written prescription include the prescriber's individual NPI in order for that prescription to be valid. But as is discussed in section II.E.11. of this final rule with comment period (Access to Covered Part D Drugs through Use of Standardized Technology and National Provider Identifiers), we believe that linking individual NPIs to specific prescriptions may provide law enforcement agencies with information that could be essential to identifying and prosecuting the particular individuals committing or abetting fraud, waste, or abuse. Accordingly, we once again would like to take this opportunity to encourage States to require that every prescription include the individual NPI of the prescriber in order to be valid under State law.

Comment: A few commenters indicated they supported or agreed with the provision.

Response: We appreciate the commenters' support of this codification of our long standing policy.

Comment: A few commenters questioned whether the proposed regulation would change existing responsibilities and asked CMS to provide additional guidance. A commenter first pointed out that pharmacies, not plans, are required by State pharmacy laws to ensure that prescriptions meet minimum State requirements and should not be held accountable if a pharmacy fails to fill a prescription pursuant to applicable laws. The commenter then requested that CMS (1) ''reiterate'' that pharmacies must ensure that prescriptions are valid; and (2) direct pharmacies to ensure that CMS mandates like NPIs are included in prescription claims sent to plans.

Response: This regulation does not in any way preempt existing State requirements or create new Federal requirements. Rather, our codification of longstanding policy merely specifies in regulation that applicable State law applies in determining whether a prescription is valid. Therefore, we disagree with the commenter's suggestion that our policy takes any position with respect to which parties are responsible for ensuring prescriptions are valid under applicable State law—the parties should look to applicable State law on that issue. However, we would like to note, as has always been the case, that it is up to each Part D sponsor to determine through its contracting management how to best ensure that its network pharmacies are complying with the Part D requirement that prescriptions be valid under applicable State law.

Comment: Several commenters asked CMS to clarify the limits on audits as related to this proposal. One of these commenters believed that prescriptions cannot be audited using more strict guidelines than State law requires and requested that CMS instruct sponsors to stop ''egregious audit practices'' against pharmacies for violations of requirements not found in State law. Requesting that CMS clarify that LTC pharmacies being audited should not be required to produce documentary proof of prescriptions under applicable State laws, another commenter expressed concern that LTC pharmacies would not be able to provide sponsors, auditors, and/or CMS with such proof valid under State law because such prescriptions are typically kept with patient charts at the LTC setting.

Response: As discussed previously, our proposal was intended to codify our longstanding policy that applicable State law applies in determining what constitutes a valid prescription and that Part D benefits should be available only for otherwise covered drugs that are dispensed upon a valid prescription. We did not propose rules governing the conduct of audits by any entities—including plan sponsors.

Comment: A commenter appreciated that CMS encouraged States to require individual NPIs for valid prescriptions. But, after observing that no States required NPIs for valid prescriptions, the commenter indicated that pharmacists would be challenged by a large number of prescriptions lacking appropriate NPIs.

Response: For a response addressing this issue, please see section II.E.11 of this final rule with comment period (Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers).

We are finalizing this provision without modification.

9. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

Section 1860D–4(c)(2) of the Act requires medication therapy management (MTM) programs to be designed to ensure that, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act (individuals as specified with multiple chronic diseases, taking multiple covered Part D drugs, and likely to incur certain annual Part D drugs costs), covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. Section 10328 of the Affordable Care Act further amended section 1860D–4(c)(2)(ii) of the Act to require prescription drug plan sponsors as part of the MTM services furnished to targeted beneficiaries to offer, at a minimum, an annual comprehensive medication review (CMR) that must be furnished person-to-person or via telehealth technologies. The comprehensive medication review must include a review of the individual's medications, which may result in the creation of a recommended medication action plan with a written or printed summary of the results of the review provided to the targeted individual.

As we reiterated in the preamble to the October 11, 2011 proposed rule, we first explained in our April 2011 final rule (75 FR 21476 through 21478) that beneficiaries residing in long term care (LTC) facilities who have cognitive impairments may not be able to participate in CMRs. The current regulations at § 423.153(d)(1)(vii)(B), which were amended in the April 2011 final rule to reflect certain requirements of the Affordable Care Act, continue to exempt sponsors from offering interactive, person-to-person consultations to targeted beneficiaries who reside in LTC settings. However, the Act, as amended by section 10328 of the Affordable Care Act, does not provide a basis for creating an exception to the requirement to offer a CMR based on the setting of care. Since the Affordable Care Act provision for MTM programs was not effective until January 1, 2013, in the April 2011 final rule, we indicated that we would undertake further rulemaking to clarify the requirements for MTM programs to offer CMRs to targeted beneficiaries in LTC settings.

In the October 11, 2011 proposed rule, we proposed to revise the regulation at § 423.153 to require sponsors to offer the annual CMR to targeted beneficiaries in an LTC facility—but when the beneficiary cannot accept the offer to participate—the pharmacist or other qualified provider must perform a CMR without the beneficiary. When the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs, we recommended that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR.

Comment: Several commenters questioned how to determine whether a beneficiary residing in an LTC setting is cognitively impaired or able to participate in the CMR and suggested that this determination should be made by or coordinated with the LTC facility or LTC consultant pharmacist. One of these commenters questioned if documentation of this determination should be maintained and another suggested revising the Part D reporting requirements to require Part D sponsors to report the beneficiaries who opted out of the CMR due to cognitive impairment.

Response: We agree that LTC consultant pharmacists are positioned to help plan sponsors work with the LTC facility staff to identify cognitively impaired beneficiaries in LTC settings and determine whether beneficiaries are capable of participating in a CMR. We recommend that plan sponsors coordinate with LTC consultant pharmacists to make these determinations. If asked, plan sponsors should be able to present documentation or a rationale for these determinations. Any changes to the Part D reporting requirements are outside the scope of this regulation.

Comment: A few commenters are opposed to the proposed policy, and a commenter argued that the CMR requirement in the LTC setting should be the responsibility of the LTC facility, not plan sponsors, because LTC facilities are paid to provide care to their patients and have their own physicians and pharmacists who order and fill the drugs.

Response: The statute specifies that ''prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries'' and requires interventions ''to increase adherence to prescription medications or other goals deemed necessary'' and includes at a minimum ''an annual comprehensive medication review furnished person-to-person or using telehealth technologies.'' Further, the Act, as amended by section 10328 of the Affordable Care Act, does not provide a basis for distinguishing the offering of a CMR based on the setting of care.

Comment: Several commenters urged CMS that in order to maximize the efficient use of healthcare resources, the CMR should be performed in the LTC setting by an LTC consultant pharmacist or that plan sponsors should coordinate with the consultant pharmacists performing monthly drug regimen review (DRR) before intervening to resolve potential medication-related problems identified through the CMR or other MTM services. Other commenters requested clarification and additional guidance on the pharmacist or other qualified provider who will perform the CMR on behalf of the targeted beneficiary in LTC settings and how this would be implemented. Another commenter questioned if the pharmacist or other qualified provider performing the CMR is permitted to be employed by the sponsor or its Pharmacy Benefits Manager (PBM) and if it is common for the MTM provider to be the PBM, and not the plan sponsor.

Response: Sponsors may utilize in-house resources or make arrangements with other resources (such as PBMs, MTM vendors, or individual pharmacists or other qualified providers) to provide MTM services and administer their MTM program to targeted beneficiaries. We agree that LTC consultant pharmacists would be a valuable resource for the delivery of CMRs to targeted beneficiaries in LTC settings, and also acknowledge that the potential overlap between the DRR reviews required in LTC settings and Part D MTM reviews could possibly result in conflicting reviews. To maximize efficient use of healthcare resources, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC. Such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and LTC consultant pharmacists (or their intermediaries). We would like to hear from any parties who may currently be doing this and how such arrangements have improved care coordination or created efficiencies. You may contact *CMS at partd_mtm@cms.hhs.gov.*

Comment: A commenter argued that when the targeted beneficiary in the LTC setting is unable to participate in the CMR, there should be an exemption from the CMR standardized format requirements.

Response: Section 423.153(d)(1)(vii)(D) of the regulations requires standardized format action plans and summaries that comply with requirements as specified by CMS for the standardized format, to be provided following each CMR. This applies whether the CMR is provided to the beneficiary, or to the authorized representative or prescriber who may take part in the CMR if the beneficiary cannot participate. If the commenter meant to suggest that no written summary be provided, we would respond that the need for a CMR is certainly no less vital when individuals are cognitively impaired and these summaries can serve to coordinate care.

Comment: A few commenters suggested that CMS consider alternative approaches to disseminating MTM recommendations in the LTC setting by, for instance, providing: (1) The findings or recommendations related to drug therapy to the attending physician and/or nursing staff at the LTC facility; (2) CMR written summaries and standardized action plans to the LTC facility; or (3) medication review results to the beneficiary's medical power of attorney, if applicable.

Response: We appreciate these recommendations. Plan sponsors and MTM providers may, but are not required to, provide copies of the CMR written summaries and medication action plans to other HIPAA-covered entities to coordinate care. Also, a HIPAA covered entity may share a beneficiary's health information (such as medication review results) with the beneficiary's personal representative, which includes a person with medical power of attorney, where that information is relevant to such personal representation.

Comment: Several commenters focused on outreach to individuals to participate in the CMR aside from the targeted beneficiary. A commenter suggested that, even when the beneficiary can participate, the provider conducting the CMR still should be able to reach out to individuals, such as the family caregiver, other authorized individual, and beneficiary's prescriber, to participate in the CMR. A few commenters suggested that when impairment prevents a targeted LTC beneficiary from participating in the CMR, CMS should require the provider arranging the CMR to provide written notice to the individual's health care proxy or legal representative, while another asked whether telephone or mail contact was acceptable. Another commenter recommended that if the targeted beneficiary in the LTC setting is unable to participate, the caregiver or surrogate should be engaged first, and then the prescriber, to ensure that the patient's best interests are protected.

Response: While we certainly appreciate an approach that would allow the beneficiary to be joined by, for instance, family members for a CMR, we believe it best, when a beneficiary is able to participate, to leave the decision as to whom he or she wishes to invite to his or her discretion. In these instances the pharmacist or other qualified provider may ask the beneficiary for permission to invite other individuals to the CMR. As to the form of the outreach, sponsors are responsible for choosing the outreach method, and are expected to use more than one approach when possible to reach all eligible targeted beneficiaries, regardless of setting, so they are able to receive MTM services and a CMR versus only reaching out via passive offers. These expectations also apply to any outreach to a beneficiary's prescriber, caregiver, or other authorized individual. Lastly, we do not believe it would be appropriate to burden the pharmacist or qualified provider arranging the CMR by specifying the order in which to contact individuals to represent a beneficiary who cannot participate in the CMR. This decision should be at the discretion of the provider and is dependent on the individual beneficiary's needs and situation.

Comment: A commenter recommended that CMS recognize that MTM services focused on the use of the most appropriate and cost-effective medications should be the primary goal of MTM in the LTC population.

Response: This comment is outside the scope of this rulemaking, and therefore, we will not address it in this rule.

Comment: A few commenters suggested that beneficiaries in other settings may be cognitively impaired or unable to participate in the CMR (such as hospice patients, beneficiaries being cared for in an assisted living facility, or at home) and the proposed rule should not be limited to targeted beneficiaries in the LTC setting.

Response: Targeted beneficiaries in other health care settings are not excluded from the Part D MTM requirements, and must be offered MTM services if eligible. The proposal to eliminate the exception to the requirement to offer a CMR for beneficiaries residing in LTC settings was necessary in order to bring the existing regulation into compliance with requirements of section 10328 of the Affordable Care Act. Accordingly, the proposed revisions to the language of § 423.153(d) would require Part D sponsors to offer CMRs to all targeted beneficiaries in all settings. We acknowledge that beneficiaries in settings other than LTC may suffer cognitive impairments. Therefore, we encourage MTM programs to adopt similar approaches to furnishing MTM services to these beneficiaries who may be unable to accept an offer of a CMR and recommend outreach to the beneficiary's prescriber, caregiver, or other authorized individual.

Comment: A commenter questioned whom the plan sponsor can contact to act on behalf of the beneficiary if a call to an LTC facility results in the plan not being able to reach a beneficiary. The commenter questioned if the plan sponsor should assume that the prescriber and/or LTC consultant pharmacist on staff can be called and a CMR can be completed.

Response: We recommend that when a targeted beneficiary moves to an LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary, which could be the prescriber, caregiver, or authorized representative. Alternatively, sponsors could include this requirement in any arrangements that may be made with the LTC consultant pharmacist in the conduct of Part D MTM services.

Comment: Several commenters requested clarification about distinguishing services provided through the existing LTC consultant pharmacist monthly DRR and those required for targeted LTC beneficiaries through Medicare Part D MTM and commented that the efforts are duplicative. Some commenters suggested that plan sponsors should rely on the consultant pharmacists' review or, alternatively, sponsors should not be required to conduct CMRs for beneficiaries in the LTC setting.

Response: As mandated by section 10328 of the Affordable Care Act, sponsors are required to offer CMRs to all targeted beneficiaries, including those in LTC settings. While there is some potential overlap between the LTC consultant pharmacist monthly DRR and MTM required for targeted LTC beneficiaries through Part D, Part D sponsors remain subject to the requirement to furnish MTM services to all targeted beneficiaries consistent with section 1860D–4(c)(2) and the regulations at § 423.153(d). Thus, services required for MTM, such as offering a CMR, which must include an interactive, person-to-person, or telehealth consultation, are required for all targeted beneficiaries, including those in LTC settings. In light of the potential overlap, and to maximize efficient use of healthcare resources, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in the conduct of Part D MTM services for targeted beneficiaries in LTC settings. We will provide guidance on the implementation of the MTM requirements and set service level expectations where necessary.

Comment: Several commenters felt that the recommendation that MTM providers reach out to the beneficiary's prescriber, caregiver, or other authorized individual to participate in the CMRs is administratively burdensome and costly given that plan sponsors cannot easily identify the LTC resident's health care proxy or authorized representative, or primary care physician (and their contact information), and question if this contact information is consistently captured or reported.

Response: As indicated in an earlier response, we recommend but do not require that when a beneficiary moves to an LTC facility, Part D plans identify the appropriate contact for each beneficiary, which could be the prescriber, caregiver, or authorized representative. Alternatively, sponsors could include this requirement in any arrangements that may be made with the LTC consultant pharmacist regarding the conduct of Part D MTM services. LTC consultant pharmacists are positioned to help plan sponsors work with LTC facility staff to identify the resident's authorized representative or prescriber, particularly in cases where this information is not part of the Part D enrollment information. We recommend that plan sponsors coordinate with LTC consultant pharmacists to obtain this information.

Comment: A few commenters requested clarification to distinguish between an interactive and non-interactive CMR and how it differs from the current MTM and interactive CMR processes.

Response: The October 11, 2011 proposed rule inappropriately referred to ''non-interactive CMRs.'' By definition, a CMR is an interactive consultation with the beneficiary or an authorized individual, such as their prescriber or caregiver, to review the beneficiary's medications and must be a real-time interaction. Per the regulation at § 423.153(d)(1)(vii)(B)(i), the annual comprehensive medication review with written summaries must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. While providers are required to offer a CMR to all beneficiaries, regardless of setting, in the event the beneficiary is cognitively impaired, the MTM provider is encouraged to reach out to other appropriate parties to participate in a CMR. However, in the event the MTM provider is unable to identify another individual who is able to participate in the CMR, or a beneficiary in any setting refuses to participate in the CMR, a CMR cannot be performed, but sponsors are required to perform targeted medication reviews at least quarterly with follow-up interventions when necessary and perform prescriber interventions. To make the distinction clear, we are adding the word ''comprehensive'' before ''medication review'' in § 423.153(d)(1)(vii)(B)(2). We are also revising § 423.153(d)(1)(vii)(B)(2) to remove the reference to beneficiaries residing in LTC settings and to state that if a beneficiary is offered the annual CMR and is ''unable to'' accept the offer to participate, the pharmacist or other qualified provider ''may'' perform the CMR ''with the beneficiary's prescriber, caregiver, or other authorized individual'' to clarify that a CMR is voluntary and that a CMR cannot be performed without participation by the beneficiary, or an individual authorized to represent the beneficiary.

Comment: A commenter requested that we delay implementation due to potential bid and cost implications that would impact contract negotiations with LTC facilities or even the pharmacy providers for LTC facilities.

Response: We cannot delay implementation of this requirement because the statute mandates that we implement section 10328 of the Affordable Care Act by January 1, 2013. Additionally, sponsors were put on notice regarding this deadline in our April 2011 final rule in which we stated our plans to undertake additional rulemaking to clarify the CMR requirements for targeted beneficiaries in LTC settings. However, we thank the commenter for highlighting that we incorrectly stated in the proposed rule that we did not anticipate any costs associated with this change. This was an oversight, and we have revised the regulatory impact and estimate to acknowledge that there will be a modest increase in costs to offer CMRs to beneficiaries residing in LTC settings with written summaries in a standardized format that complies with the requirements specified by CMS.

After consideration of the comments received in response to this final rule with comment period, we are adopting the revisions to § 423.153(d)(1)(vii)(B) as proposed with the clarifying changes discussed previously. The revisions will become effective January 1, 2013.

10. Employer Group Waiver Plans Requirement To Follow All Part D Rules Not Explicitly Waived (§ 423.458)

The Secretary has the statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored prescription drug plans (PDPs). Both employers/unions that contract directly with CMS, as well as PDP sponsors that contract with employers/unions and CMS, may offer customized employer group PDPs which are referred to collectively as employer/union-only group waiver plans (EGWPs). The statutory authority, set forth in section 1860D–22(b) of the Act, provides that the provisions of section 1857(i) of the Act shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to that in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to Part D eligible individuals enrolled in such coverage.

Under this statutory authority, in order to facilitate the offering of PDPs to employer/union group health plan sponsors, we may grant waivers and/or modifications to PDP sponsors. In general, each waiver or modification that we grant is conditioned upon the PDP sponsor meeting a set of defined circumstances and complying with a set of conditions. PDP sponsors offering EGWPs must comply with all Part D requirements unless those requirements have been specifically waived or modified.

It has come to our attention that some EGWPs that provide Part D benefits to their members may not be affording their members appropriate Medicare beneficiary protections put in place by CMS regulations or guidance. Based upon discussions we have had with sponsors of EGWPs, some sponsors believe they are exempt from Part D requirements when providing Part D benefits because of the CMS waiver of the requirement that EGWP sponsors submit plan benefit packages for CMS review (see section 20.9 of Chapter 12 of the Medicare Prescription Drug Benefit Manual). Regardless of whether plan benefit packages are submitted for review, Part D sponsors of EGWPs must meet all Part D requirements (regulatory or legislative) unless such requirements are specifically waived or modified by CMS. Therefore, in order to emphasize the importance of providing EGWP members with beneficiary protections put in place by Part D requirements, we proposed to revise § 423.458 by adding a new paragraph (paragraph (c)(3)) to clearly state that in the absence of a CMS approved waiver, all Part D requirements apply and, in the case of a CMS approved waiver that modifies the application of Part D requirements, such requirements must be met as modified by the waiver.

Comment: While supporting the clarification, a commenter opined that significant operational challenges exist for EGWPs as they try to meet Part D requirements in areas including enrollment, formulary requirements, and transition fill policy. The commenter requested that CMS establish a forum and process for stakeholders such as EGWPs and employer groups to raise these issues and re-evaluate the current Part D requirements in consultation with stakeholders. In calling for transparency and efficiency, it further requested that CMS publish the outcome of waiver requests.

Response: We thank the commenter for the support and appreciate that EGWPs and EGWP sponsors face unique operational issues. We have already established a forum for stakeholders to raise Part C and D concerns—the biweekly Part C & D user call—and we would welcome any questions or concerns that EGWPs, EGWP sponsors, employer groups, or other interested stakeholders might care to raise. Stakeholders can email inquiries to the Part C & D user call at *PartDBenefitImpl@cms.hhs.gov.*

As to the suggestion that we publish the outcome of waiver requests, Chapter 12 of the Prescription Drug Benefit Manual (and Chapter 9 of Medicare Managed Care Manual) describes approved waivers current as of the date of publication; we also post Part D waivers when approved by CMS through HPMS. We will take the suggestion to publish requests for waivers that are denied under consideration.

We are finalizing the provision as proposed with one modification. In § 423.458, the new paragraph will be designated as paragraph (c)(4) instead of (c)(3).

11. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

Every time a beneficiary fills a prescription under Medicare Part D, a sponsor must submit to CMS an electronic summary record called a prescription drug event (PDE). We require that Part D sponsors obtain and submit a prescriber identifier on PDE records. Every prescriber has at least one identifier that can be submitted. These identifiers include the National Provider Identifier (NPI), Drug Enforcement Administration (DEA) number, uniform provider identification number (UPIN), or State license number. In a June 2010 report titled, ''Invalid Prescriber Identifiers on Medicare Part D Drug Claims,'' the OIG reported the findings of its review of prescriber identifiers on 2007 Part D PDE records. The OIG reported finding 18.4 million PDE records that contained 527,749 invalid identifiers, including invalid NPIs, DEA registration numbers, and UPINs. Payments by Part D drug plans and enrollees for these PDE records totaled $1.2 billion.

In light of this report, we signaled in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Letter issued on April 4, 2011 (''CY 2012 Call Letter'') that we were considering a regulatory change in the Part D program that would limit acceptable prescriber identifiers on claims and PDE records in 2013 to only the individual NPI. We indicated that since all practitioners who are authorized to prescribe Part D drugs under applicable U.S. State laws, including foreign prescribers whose prescriptions are valid in certain States, can acquire an individual NPI from HHS, we do not believe such a change would present a significant access barrier to needed Part D drugs for Medicare beneficiaries.

Not only can all practitioners who are authorized to prescribe Part D drugs under applicable U.S. State laws acquire an NPI from HHS, but most are required to do so. Pursuant to HIPAA, HHS adopted the NPI as the standard for uniquely identifying health care providers in electronic transactions in the final rule published on January 23, 2004 (69 FR 3434), which was effective May 23, 2005, the date on which all health care providers, broadly defined in 45 CFR 160.103, became eligible for NPIs. By May 23, 2008, all covered health care providers, defined in 45 CFR 162.402, must have obtained an NPI. Covered health care providers must disclose their NPI to other entities that need the NPI for use in standard transactions.

Health care providers who are not covered entities are not required to obtain and disclose NPIs, but HHS encourages them to do so in the NPI final rule (January 23, 2004, 69 FR 3445). Therefore, we believe there are very few prescribers who do not already have an individual NPI that they will disclose to Part D sponsors and/or their network pharmacies who need it for standard transactions, with the exception of foreign prescribers, whom we discussed in greater detail later in this section of the final rule with comment period. In addition, for those health care providers who do not already have an NPI, obtaining one is not a burdensome endeavor and is free of charge.

As a measurable indicator, approximately 90 percent of Medicare Part D claims as reported in 2011 prescription drugs events (PDEs) submitted to CMS contain valid individual prescriber NPIs—a uniform identifier—even though CMS permits alternate prescriber IDs at this time. However, while the vast majority of Medicare Part D claims contain individual NPIs as of coverage year 2011, 10 percent still do not, and CMS believes it is important for prescribers to be identified in a consistent, verifiable manner in order to conduct appropriate oversight of the program.

The consistent use of a single validated identifier would enable us to provide better oversight over possible fraudulent activities. More specifically, CMS, MEDICs, and oversight agencies would be able to more efficiently identify patterns of unusual prescribing that may be associated with fraudulent activities. When multiple prescriber identifiers, not to mention default, dummy or invalid identifiers, are used, authorities must take an additional step in their data analysis before even achieving a refined data set to use for further analysis to identify possible fraud. For example, having to cross-reference multiple databases that update on different schedules to be certain of the precise prescribers involved, when multiple identifiers were used, would necessitate several additional steps of data pre-analysis and also would introduce potential errors in correctly matching prescribers among databases.

In light of the foregoing, we proposed to amend § 423.120(c) to require, effective January 1, 2013, that Part D sponsors must submit an active and valid individual prescriber NPI on any PDE record submitted to CMS. This requirement would enhance our efforts to use claims data to identify fraud in furtherance of section 1893 of the Act, which established the Medicare Integrity Program and the Secretary's obligations with respect thereto. In addition to supporting CMS fraud and abuse activities, accurate data on prescriptions through the consistent use of valid NPIs on PDEs allows CMS to serve beneficiaries when using data in various initiatives whose purpose is to foster higher quality and more efficient coordination of care for individuals and groups of individuals.

We also proposed that sponsors may not reject a pharmacy claim solely on the basis of the lack of a valid prescriber NPI, unless the issue can be resolved at point-of-sale (POS), in order not to impede Medicare beneficiary access to needed medications. In other words, we proposed that Part D sponsors may not reject pharmacy claims at point of sale without prompt follow-up to ensure that the claim has been resubmitted by the network pharmacy with a corrected and valid individual prescriber NPI, or new information has been otherwise received to correct the sponsor's information.

Our proposal meant that if a correct and valid individual prescriber NPI is not included in the pharmacy claim, and it is determined that the prescriber does not have one and the claim is otherwise payable (for example, no indication of fraud, such as a prescription written by a provider excluded from the Medicare program, or no question regarding coverage), the sponsor must pay the claim, but cannot submit the PDE to CMS. Thus, if an active and valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire an active and valid ID before the PDE may be submitted to CMS. As noted previously, we believe prescribers' NPIs will be widely available to Part D sponsors.

We reminded Part D sponsors that the requirements proposed were on sponsors, whose responsibility it would be to submit PDEs to CMS with individual prescriber NPIs. Therefore, we stated that we would expect that network pharmacies will be permitted to correct any invalid data before payment for a claim is reversed, if the contract allows such a reversal. Additionally, we stated that we would expect that any requirement by a plan sponsor or its contracted PBM on a pharmacy to acquire and utilize its own automated validation capability will be arrived at only through mutual agreement, since such a requirement may be unaffordable for many smaller pharmacy organizations. For the reasons discussed in the following comment and response section, in response to comments, we are modifying the regulation text to better accomplish these policy goals.

With respect to requests for reimbursement submitted directly by Medicare beneficiaries, we proposed that requests for reimbursement from Medicare beneficiaries be handled in the same manner by Part D sponsors as claims from pharmacies. Thus, we proposed that sponsors may not make payment to the beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid NPI in connection with a request for reimbursement submitted by a beneficiary, we proposed that the sponsor may not seek recovery of the payment from the beneficiary solely on that basis, unless there is an indication of fraud.

We had learned from stakeholders through a contractor to CMS that a key barrier to improved NPI reporting on Part D PDEs is that CMS does not currently require NPI reporting, and our proposal was thus responsive to those observations. In addition, some pharmacy representatives have offered that certain States require or accept other prescriber identifiers, which impedes NPI reporting at the pharmacy level. It is unclear to us whether the latter observation was in the context of States as regulators of prescriptions or as payers of claims or both, and which alternate identifiers are required or accepted by these States. Therefore, we sought specific comment on this issue to assist us in understanding and confirming any State-imposed barriers to the standardization of prescriber identifiers to the individual NPI for the Medicare Part D program. We did not receive any such comments.

We stated that we considered exercising the discretionary authority granted pursuant to section 6405(c) of the Affordable Care Act so that prescriber NPIs would be required on Part D claims and PDEs. However, such an approach would require prescribers to also enroll in the Medicare program, which is a provider credentialing process. Thus, we were concerned that requiring such enrollment could impede Part D beneficiary access to needed medications, because the process involves more effort on the part of prescribers, who are not reimbursed for prescriptions, compared to obtaining an NPI, which involves a three page application form that primarily seeks only identifying and location information and is free of charge. We stated that since we know that prescribers will also be concerned about beneficiary access to medications, we believed virtually all prescribers who do not already have an NPI would actually obtain one, but we are not certain this would be the case with respect to Medicare enrollment.

Regarding foreign prescribers, we stated our understanding that seven States (Arizona, Florida, Maine, North Dakota, Texas, Vermont, and Washington) currently permit pharmacies to fill prescriptions from foreign prescribers, to varying degrees. We stated our belief that foreign prescribers may not have sufficient incentives in terms of patient base or familiarity with health care reimbursement in the United States, particularly with respect to the Medicare program and Part D benefits, to obtain individual NPIs. Thus, unlike our guidance in the CY 2012 Call Letter, and in contrast to our proposal with respect to domestic prescribers, we did not propose to require Part D sponsors to cover claims involving foreign prescribers without an active and valid individual prescriber NPI. The motivation for our individual prescriber NPI proposal stems in large part from our need for consistent data to conduct better oversight over possible fraudulent activities in the Medicare Part D program. Since the Federal government has no jurisdiction over foreign prescribers, we proposed an exception to our proposal that the sponsor must pay an otherwise payable claim for a prescription, but cannot submit the PDE to CMS, without an individual prescriber NPI, when the claim involves a foreign prescriber who does not have an individual NPI. Thus, we proposed a Part D sponsor could reject a claim involving a foreign prescriber who does not have an NPI at point-of-sale without additional follow-up requirements.

In fact, in light of our lack of jurisdiction over foreign prescribers and our motivation to conduct better oversight over possible fraudulent activities, we stated that we were considering whether the proposal with respect to foreign prescribers was broad enough and whether we should instead revise the Medicare Part D rules to prohibit sponsors from paying claims that involve prescriptions written by foreign prescribers, regardless of whether the foreign prescribers obtain an individual NPI. We noted that we were not making such a proposal, but solicited specific comments on foreign prescribers and the Part D program. However, we received no comments on this alternative to the foreign prescriber issue, and therefore we are finalizing our original proposal as to foreign prescribers.

Comment: Some commenters acknowledged the need for a single, validated prescriber identifier on PDEs. A commenter elaborated that our proposal would streamline prescriber identifier validation and enhance the ability to more effectively track and validate prescription activity at the individual prescriber level, which will assist in the identification of potentially fraudulent or inappropriate claims, as well as in improve the quality of patients' therapeutic outcomes.

Response: We agree with these comments. In addition to assisting us, we believe our proposal will result in a more streamlined prescriber validation process for Part D sponsors, PBMs, and network pharmacies. Routine use of a single identifier will minimize validation costs and efforts for all entities that collect, review and utilize this data.

Comment: Some commenters reiterated our observation that not all prescribers have to obtain an NPI and use it, in particular medical interns and residents, and these commenters stated that interns and residents have often used group or supervisor NPIs on prescriptions. Other commenters stated it was unfair for Part D sponsors to shoulder the burden of claims for which there is not an active and valid prescriber NPI. Another commenter stated conversely that, due to the standards described in the CY 2012 Call Letter regarding prescriber identifiers, nearly all claims submitted by pharmacies to Part D sponsors will contain prescriber NPIs by 2013.

Response: As part of our observations in the proposed rule, we stated that we believe there are actually very few prescribers who either do not have, or would be unwilling to obtain, an individual NPI that they will disclose to Part D sponsors and/or their network pharmacies who need it for standard transactions in order to facilitate their Medicare patients' access to needed medications. Moreover, nothing prevents a sponsor from requesting a prescriber to obtain and disclose an NPI to facilitate a delayed submission of a PDE. Nevertheless, other strategies are being explored which would require prescribers who are not currently required to obtain NPIs to be required to obtain them. We agree with the commenter that there will be very few instances in which a Part D sponsor would not be able to submit a PDE to CMS due to the lack of an active and valid individual prescriber NPI.

Comment: A commenter stated that our request that payers not reject a claim from a network pharmacy for lack of an active and valid NPI (unless the issue can be resolved at point of sale) and retrospectively obtain one, could result in a retroactive denial of the claim, and that this scenario would not adhere to NCPDP's definition of a paid response. That is, if the sponsor has or should have had reason to believe that the identifier on the submitted claim is invalid or not active, but submits a paid response in such circumstances, this response would be inconsistent with HIPAA transaction standards, pursuant to which a paid response may be sent only when the claim satisfies the payer's requirements for payment. Another commenter stated that the ''unless the issue can be resolved at point-of-sale'' standard is very unclear.

Other commenters, while acknowledging the beneficiary access issue should still be considered, requested that we modify the final rule to allow Part D plans greater flexibility to implement measures to address claims lacking an active and valid NPI, such as claim rejection at POS, in order to alert the pharmacy of this fact, and to allow for two-way communication between the parties when there is an inconsistency between prescriber identifier databases at the time when the inconsistency is most readily resolved.

Some commenters expressed appreciation and support for our statements regarding the fact that the requirement to obtain an active and valid NPI is imposed on sponsors and our expectation that sponsors would provide opportunities for network pharmacies to correct any invalid data before recouping any payment. These commenters also appreciated and supported our statements regarding any requirements by Part D sponsors/PBMs for the pharmacies to acquire automated validation capability to be mutually negotiated. However, these commenters stated that the practical effect of our proposal not to allow claims rejection at POS would be that network pharmacies will be forced to bear recoupment of claims paid by Part D sponsors, when active and valid NPIs cannot be obtained retrospectively, even when they have done nothing wrong. These commenters further stated that pharmacies must generally dispense a medication if the Part D plan provides coverage under their contact, and they are furthermore not in a position to refuse these Part D plan/PBM terms, nor terms requiring pharmacies to obtain a valid NPI for the claim to be payable, which will impose additional costs on many pharmacies, particularly smaller ones. A commenter stated that some Part D plans are already imposing requirements above and beyond current Federal regulations by recouping pharmacy reimbursement unless the underlying claims contain a valid individual NPI.

Response: Our proposed policy that payers not reject a claim from a network pharmacy for lack of an active and valid NPI (unless the issue can be resolved at point of sale) and to retrospectively obtain one was to ensure beneficiary access to needed medications in cases when the NPI issue could not be resolved at point-of-sale. We believed this scenario would be rare, and that most NPI issues could and would be resolved at point-of-sale. We have been even more persuaded by commenters that real time notification of a possible NPI issue or error is the most efficient process, since the pharmacy is in the best position to acquire corrected information from the beneficiary and/or prescriber when filling the prescription. This is because we believe the pharmacy representative is most motivated to check available data or contact the prescriber in order to get the claim adjudicated. Similarly, a prescriber is most motivated to disclose a missing NPI when the pharmacy is trying to dispense the drug prescribed to his or her patient.

In addition, in light of the comments received that our proposal did not allow for claim rejection at POS (even though this is a misunderstanding of our proposal), we are concerned that this proposed provision would be implemented by Part D sponsors in such a manner that sponsors will not undertake efforts at POS to resolve the NPI issue. We are concerned that sponsors will indicate to network pharmacies that claims lacking an active and valid individual prescriber NPI are payable, when the sponsors actually have reason to believe that the NPI is not active and valid, and then later recoup payment from the pharmacies pursuant to their agreements. We were especially persuaded by the commenter who stated that such a scenario would not adhere to NCPDP's definition of a paid response. That is, if the sponsor has reason to believe that the identifier on the submitted claim is invalid or not active, but submits a paid response in such circumstances, this response would be inconsistent with HIPAA transaction standards, pursuant to which a paid response may be sent only when the claim satisfies the payer's requirements for payment.

For these reasons, and in response to comments, we are revising our policy and the regulation text to require a Part D sponsor to ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug. Sponsors will be required to so ensure in the following manner: (1) A sponsor must communicate at point-of-sale whether or not the prescriber NPI is active and valid; (2) if the sponsor communicates that the prescriber NPI is not active and valid, the sponsor must permit the pharmacy to confirm that the NPI is active and valid, or in the alternative, to correct it; (3) if the pharmacy confirms that the prescriber NPI is active and valid or corrects it, the sponsor must pay the claim if it is otherwise payable; and (4) if the pharmacy cannot or does not correct or confirm that the prescriber NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

We would expect the back-and-forth between a sponsor and network pharmacy described previously to take no more than 24 hours, which means that sponsors will have to have controls in place to make sure network pharmacies resubmit claims where the sponsor has communicated an issue with the NPI and a pharmacy cannot or does not correct or confirm that the NPI is active an valid. We note that in practice today, pharmacy customers are not infrequently asked to return to the store later the same day or the next to pick up a prescription to allow time to resolve a claim adjudication or stock replenishing issue. Thus, we would consider a 24-hour timeframe to be timely access to outpatient medications. We also note that it is standard retail pharmacy practice to dispense a few doses of medication when these delays occur if the customer needs immediate access to the drug.

We believe these revisions preserve our policy that beneficiaries not be denied access to needed medications, while making it clearer that the requirement to obtain active and valid prescriber NPIs is imposed on Part D sponsors. At the same time, we believe these revisions respond to commenters' concerns by clarifying what we meant when we stated that NPI issues must be resolved at point-of-sale. In addition, in response to commenters' concerns that pharmacies will be unscrupulously subjected to payment recoupment for claims that do not contain an active and valid NPI when the requirement to obtain one is on sponsors, we are further revising the regulation text to state that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor: (1) Has complied with the POS requirements previously described ; (2) has verified that a submitted NPI was not in fact active and valid; and (3) the agreement between the parties explicitly permits such recoupment. We believe that this revision will further ensure that Part D sponsors engage in the point-of-sale NPI validation that we are requiring for the reasons stated previously.

Comment: A commenter requested that we instruct Part D plans that they are not allowed to mandate the use of individual NPIs on Part D claims. Other commenters requested that CMS do just that.

Response: Because this rule requires Part D sponsors to submit an active and valid prescriber NPI with a PDE, Part D sponsors may require that the NPI be submitted on claims by network pharmacies. However, as described previously, Part D sponsors will be required to communicate at the point-of-sale about the status of the NPI and will, under certain circumstances, be required to pay an otherwise payable claim, even if it does not contain an active and valid prescriber NPI.

Comment: Some commenters stated that following up with prescribers to obtain NPIs creates an administrative burden on plans, especially when considering CMS PDE submission requirements.

Response: We agree that this requirement imposes a new administrative burden on Part D sponsors. However, as we have stated previously, we believe that it is important to ensure that we have active and valid individual prescriber NPIs to allow us to better combat fraud and abuse. Therefore, we believe the benefit of this requirement outweighs the burden. Moreover, we expect that prescribers will readily respond to both pharmacy and sponsor activities to correct invalid data, and that any corrective action needed will substantially and rapidly decline over time, thus decreasing the burden on all parties. In light of the revision to our proposal to require NPI validation by sponsors at point-of-sale, as described previously, we believe there will be relatively little additional follow-up administration effort required on the part of sponsors that would interfere with timely PDE submission to CMS.

Comment: A few commenters requested clarification of the meaning of ''active and valid.''

Response: By an ''active and valid'' NPI, we mean that the NPI number is in the expected format/sequencing for such numbers and is listed as an active identifier in the National Plan and Provider Enumeration System (NPPES).

Comment: A commenter stated that we should prohibit group NPIs from being used on Part D prescriptions. Other commenters stated that prescribers should have to use individual NPIs on their prescriptions.

Response: Prescriptions are regulated by State law as noted in section II.E.8. of this final rule with comment period. We do not regulate prescriptions. At this time, we are not aware of any State that requires each electronic or written prescription to include the prescriber's group or individual NPI in order for that prescription to be valid. However, we would again like to take this opportunity to encourage States to require that every prescription include the individual NPI of the prescriber in order to be valid under State law.

Comment: Some commenters stated that CMS should notify all prescribers that pharmacies cannot fill Part D prescriptions unless they provide an active and valid individual NPI.

Response: We encourage sponsors not to permit their network pharmacies to refuse to accept prescriptions when a prescriber has not disclosed an active and valid NPI, although we cannot prohibit a pharmacy from independently doing so. However, we do not anticipate that pharmacies will engage in this practice, as we have revised this requirement so that sponsors must provide information at POS regarding whether a submitted NPI is not active and valid, and to prohibit recoupment by the sponsor if it has not provided this information. Thus, since pharmacies will have an opportunity to correct or resolve apparent discrepancies concerning the validity of NPIs, and if they do, will not be subject to recoupment, we believe pharmacies will be able to manage the risk of nonpayment by sponsors and will not refuse prescriptions. Also, options are being explored to require NPIs for those few prescribers who are not currently required to obtain NPIs, and who do not voluntarily do so, in order to facilitate their patient access to Part D drugs, even though we believe there are very few prescribers in this category.

Comment: A commenter believed that our proposal would actually undermine its purpose to achieve better oversight over possible fraudulent activities, as well as other program oversight objectives, since PDE records would no longer constitute a comprehensive database of drugs covered under the Part D program. In other words, we understood this commenter to assert that plans will not submit significant numbers of PDEs for lack of an active and valid prescriber NPI.

Response: We disagree. As noted previously, most prescribers already have and disclose NPIs, and we believe that number will increase after current efforts in 2012 to correct invalid prescriber identifiers on file with pharmacies. Also, options are being explored to require NPIs for those few prescribers who are not currently required to obtain NPIs, and who do not voluntarily do so, in order to facilitate their patient access to Part D drugs. Thus, we believe the commenter's projected risk of sponsors not submitting PDE records due to missing or invalid NPIs, leading to incomplete Part D drug utilization records on file with CMS, will not materialize.

Comment: Several commenters stated that there is no single, thorough, complete, and accurate database that contains up to date and validated prescriber NPIs, including NPPES, which also lacks all the data elements needed, such as DEA numbers, which causes editing issues in a real-time adjudication environment. One of the commenters stated that NPPES information should be disseminated and available to plans on a weekly basis, with deactivated NPIs noted, including the rationale for and date of deactivation. This commenter also stated that CMS should work with HHS Office of Inspector General (OIG) to ensure excluded individuals are identified in NPPES, as well as to create an NPI reference on the HHS–OIG excluded provider list.

Response: The primary purpose of the NPPES is to collect information needed to uniquely identify individual and organization health care providers, assign NPIs to those health care providers, maintain and update the information about the health care providers, and disseminate the information according to the NPPES Data Dissemination Notice. NPPES data is available to the public via the NPI Registry and is updated daily. In addition to the NPI Registry, CMS provides a monthly NPPES downloadable file.

NPPES was designed in a way to meet its intended purpose in the most feasible way and was not intended to be a one-stop database for all prescriber identifiers. Also, sanction data were not included in the data element list published in the final NPI rule published January 23, 2004, and therefore, are not included in the NPPES data element list today. However, we do acknowledge the advantages of the additional information desired by sponsors, such as the date and reason for deactivation of an NPI, and we are exploring the feasibility of improving the information available regarding the deactivated NPIs.

Comment: A commenter stated that a grace period should be allowed to address the processing of claims with deactivated NPIs, such as when a prescriber has retired or passed away. This commenter suggested that rather than rejecting the claims, sponsors could send an information edit to notify pharmacies of the time period when it will begin to reject claims that contain the prescriber NPI, and pharmacies could then inform beneficiaries to find a new prescriber with an active individual NPI.

Response: An informational edit during a grace period for an NPI deactivated due to death or retirement might be a prudent practice, since we understand some States permit refills when the prescription was written before the prescriber's retirement or death. We will provide additional guidance in the future, if necessary on this point. We take no position on whether a pharmacy should encourage a beneficiary to find a new prescriber with an active NPI.

Comment: A commenter supported the proposal to not permit recovery of beneficiary payment on beneficiary-submitted requests for reimbursement when retroactive acquisition of the prescriber NPI has not been successful, as a means to protect beneficiary access to drug therapy prescribed by his or her physician. Another commenter was pleased that beneficiaries will not be negatively impacted by such lack of an NPI for a PDE.

Response: We appreciate the support for our proposal.

Comment: A commenter was pleased that we chose not to require Medicare Part D prescribers to enroll in Medicare which supports beneficiary access and obviates the need for physicians to engage in a credentialing process for which they are not compensated.

Response: We appreciate the support for our proposal.

Comment: A few commenters supported our proposal regarding foreign prescribers. Another commenter stated the proposal was essential for prohibiting claims payment on prescriptions involving foreign prescribers. One commenter noted that there is no database of foreign prescribers.

Response: We thank the commenters for their support. Under our proposal, as revised in response to other comments, if a foreign prescriber has an active and valid NPI that is submitted on the claim, a Part D sponsor must pay the claim, if it is otherwise payable and applicable State law permits prescriptions from foreign prescribers. However, if the NPI is not active and valid and the pharmacy cannot correct the NPI for a foreign prescriber, then the sponsor does not have to require the pharmacy to resubmit the claim (when necessary) and is not required to pay it (if it is otherwise payable). This is consistent with our proposal that sponsors could not reject a claim lacking an active and valid NPI unless the claim involved a prescription written by a foreign prescriber. We acknowledge that there is no database of foreign prescribers; however, we do not believe the lack of such a database would hinder sponsors' compliance.

Comment: Some commenters requested a delay in the NPI requirement.

Response: We were not persuaded by the comments we received that we should delay the prescriber NPI requirement for PDEs. In particular, we considered that ninety percent of PDEs as of coverage year 2011 already contain prescriber NPIs, according to CMS data, and weighed that against the importance of a single prescriber identifier to assist in fighting potential fraud in the Part D program.

After consideration of the public comments received, we are finalizing our proposal with the modifications noted previously.

Section 423.120(c) sets forth the responsibilities of Part D plan sponsors with regard to the use of standardized technologies and compliance with the HIPAA standards at 45 CFR 162.1102. We are adding a new paragraph (c)(5)(i) which requires Part D plan sponsors to submit to CMS only PDE records that contain an active and valid individual prescriber NPI. However, new paragraph (c)(5)(ii) will require a Part D plan sponsor to ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug by taking the steps described in a new paragraph (c)(5)(iii). New paragraph (c)(5)(iii) requires that the sponsor communicate at point-of-sale whether or not a submitted NPI is active and valid; paragraph (c)(5)(iii)(A)(1) and (2) will require, if the sponsor communicated that the NPI is not active and valid, that the sponsor must permit the pharmacy to confirm that the NPI is active and valid, or in the alternative, to correct it. If the pharmacy confirms that the NPI is active and valid or corrects the NPI, paragraph (c)(5)(iii)(B)(1) will require the sponsor to pay the claim, if it is otherwise payable. Paragraph (c)(5)(iii)(B)(2) will require, if the pharmacy cannot or does not correct or confirm that NPI is active and valid, that the sponsor must require the pharmacy to resubmit the claim (when necessary), which claim the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

New paragraph (c)(5)(iv) will prohibit a Part D sponsor from later recouping payment to a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one unless the sponsor: (1) Complied with paragraph (c)(5)(ii) and (iii); (2) verified that a submitted NPI was not in fact active and valid; and (3) the agreement between the parties explicitly permits such recoupment.

New paragraph (c)(5)(v) will prohibit a Part D sponsor, with respect to requests for reimbursement submitted by Medicare beneficiaries, from making payment to the beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. It will further prohibit a Part D sponsor from seeking recovery of any payment to the beneficiary on the basis that the sponsor was unable to retrospectively acquire an active and valid individual prescriber NPI, unless there is an indication of fraud. As noted previously, these changes would be effective for PDEs submitted by Part D sponsors on January 1, 2013 or later.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain paperwork burden but not all of them are subject to the PRA for reasons noted.

A. ICRs Regarding the Coverage Gap Discount Program (§ 423.100, § 423.505(b), § 423.1002, and Part 423 Subpart W)

Section 1860D–14(d)(6) of the Act exempts this section from PRA requirements.

B. ICRs Regarding the Inclusion of Benzodiazepines and Barbiturates as Part D Drugs (§ 423.100)

In accordance with section 175 of MIPPA, which amended section 1860D–2(e)(2)(A) of the Act, we proposed to revise the definition of Part D drug at § 423.100 to include barbiturates when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines, effective January 1, 2013.

Part D plan sponsors will be required to submit information in their formulary files indicating that they will cover these drugs. The collection of information burden on Part D sponsors imposed by this proposed regulation is negligible. Any burden associated with the requirement on sponsors relates to the required data entry in the formulary file software, and will be included in the PRA package entitled, Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) for Contract Year (CY) 2013 (OCN 0938–0763).

Comment: A few commenters believed that they would be burdened because they would need to apply prior authorization to determine whether barbiturates covered specific indications. A commenter pointed to an increased number of appeals, while the other foresaw an increased number of documents related to indication determinations. A commenter also noted that the change would impact SNPs because these medications are typically available without prior authorization under their medical assistance benefit.

Response: It is outside of the scope of this proposed rule to comment on the use of prior authorization for this purpose. However, we do not believe that this inclusion will increase the burden of any plan in any significant way because sponsors must always ensure that they cover drugs only when used for medically accepted indications. Making this determination is no different for barbiturates than for other drugs. As to the SNP concerns, we are complying with the statutory requirement, and because Part D coverage requirements for SNPs are not different from those for other MA–PDs, this requirement applies consistently across plan types.

After considering the public comments received, we are finalizing the policy without modification.

C. ICRs Regarding Pharmacy Benefit Manager's Transparency Requirements (§ 423.514)

Consistent with the statutory requirements under section 1150A(b)(3), we proposed to add an additional data element to the DIR data reporting requirements: aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays retail and mail order pharmacies, also known as PBM spread. In the 2010 DIR reporting requirements, we collected PBM spread amounts aggregated to the plan benefit package level. We believe that with the addition of PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies to the existing DIR reporting requirements, Part D sponsors will meet the requirements to report the elements in § 423.514(d)(4) through (6). Beyond this change, no additional DIR reporting will be required pursuant to section 1150A of the Act. We did not receive any comments on increased burden due to reporting PBM spread. We are finalizing as proposed reporting of this data element, also known as PBM spread.

In addition, section 1150A(b)(1) of the Act requires PBMs and Part D sponsors to report the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate) by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy). We explored the ideas commenters submitted for CMS to provide crosswalks or derive the pharmacy type data from existing data sources and determined that we could crosswalk National Provider Identifiers with a file from the National Council for Prescription Drug Programs to determine the percentage of all prescriptions that were provided through retail pharmacies as compared to mail order pharmacies as required under § 423.514(d)(2). However, this approach cannot be used to categorize independent, chain, supermarket, and mass merchandiser pharmacies because they are not standard pharmacy classifications captured in industry databases or files. Thus, while we are finalizing § 423.514(d)(3) as proposed, we will issue further subregulatory guidance regarding this reporting requirement before requiring Part D sponsors to submit this information.

D. ICRs Regarding Good Cause and Reinstatement Into a Cost Plan (§ 417.460)

Our proposal in § 417.460 extends reinstatement rights currently in place for members of MA and Part D plans to members of cost plans. Because good cause determinations would be made by CMS (or its contractor), we believe that this rule would not impose any new information collection requirements. We received no comments on the cost burden of the collection of information requirements related to this proposal and therefore are finalizing this provision without modification.

E. ICRs Regarding Requiring MA Plans Issuance of Member ID Cards (§ 422.111)

Under our authority at section 1852(c) of the Act to require that MA organizations disclose MA plan information upon request, as well as our authority under section 1857(e) of the Act to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed to expressly require MA plans issue and re-issue as necessary a MA member ID card that enables enrollees to access all covered services. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). That is, the time, effort, and financial resources necessary to comply with the requirement would be incurred by MA organizations in the normal course of their business activities.

F. ICRs Regarding Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

We are amending a calculation at § 423.56 to be consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d) and to change the term ‘‘CMS actuarial guidelines’’ to read ‘‘CMS guidelines’’ to allow CMS further flexibility in issuing interpretive guidance on these requirement. There is no new information collection burden on organizations.

We received no comments on the cost burden of the collection of information requirements related to this proposal and therefore are finalizing this provision without modification.

G. ICRs Regarding Who May File Part D Appeals With the Independent Review Entity (§ 423.600 and § 423.602)

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

H. ICRs Regarding CMS Termination of Health Care Prepayment Plans (§ 417.801)

This section does not impose any new information collection requirements.

I. ICRs Regarding Termination or Non-Renewal of a Medicare Contract Based on Consistent Poor Plan Performance Ratings (§ 422.510 and § 423.509)

It is our position that 3 years' worth of low-star ratings constitutes a sufficient basis for us to terminate a sponsor's Part C or D contract under our' authority under section 1857(c)(2) of the Act. The regulation has been changed to reflect that.

Regarding ICRs, we are not imposing any new reporting requirements. We are merely harnessing and putting to use internal data that has already been collected. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

J. ICRs Regarding Denial of Applications Submitted by Part C and D Sponsors With a Past Contract Termination or CMS-Initiated Non-Renewal (§ 422.502 and § 423.503)

We have modified the past performance review period described in § 422.502(b) and § 423.503(b) (by adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) as well as § 422.502(b)(4) and at § 423.503(b)(4)) to include among the factors that may support a CMS denial of a contract application those CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application.

We are not imposing any new reporting requirements. We are merely further refining our intended approach to using past performance in making application determinations. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

K. ICRs Regarding New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs) (§ 422.102)

Under § 422.102(e), we would allow certain dual SNPs meeting a high standard of integration and minimum performance and quality based standards, the flexibility to offer supplemental benefits beyond those that we allow for all other MA plans. We would review each qualified SNP's proposed supplemental benefit offerings as part of our review of plan bids, and we would approve additional supplemental benefit offerings for these qualified SNPs as we deem necessary. The burden associated with this proposed requirement is the time and effort necessary for SNPs to submit their benefit designs, including cost-sharing amounts, via the PBP software. The collection of benefit design information via PBP software is currently approved under OCN 0938–0944. We are seeking to revise this control number to incorporate the additional use of this information that is described in this section of the final rule with comment period.

Additionally, in order to evaluate how D–SNPs are implementing this new benefit flexibility, we indicate that we will require D–SNPs that participate in this new benefit flexibility initiative to submit a mandatory quality improvement project (QIP) on measures related to the goals of this initiative, as determined by CMS. The burden associated with this requirement is the time and effort that qualifying D–SNPs would put forth to develop and submit a QIP, which is currently approved under OCN 0938–1023 (CMS form #10209). We are assuming that this process would be completed by one MA organization staff person receiving a median hourly wage rate of $37.58, which is equivalent to the median hourly wage rate that the BLS currently reports for a management analyst. Adding the standard OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, we estimate an hourly cost of $55.61 to comply with this requirement. Based on our existing estimates of the QIP submission burden, we estimate that it would take each SNP approximately 15 hours to complete each QIP, resulting in an aggregate burden of 1,095 hours (15 hours multiplied by 73 D–SNPs) for the 73 D–SNPs that we believe may qualify to offer additional supplemental benefits under this new benefit flexibility initiative. Therefore, we estimate that D–SNPs participating in this initiative will incur an aggregate cost of $60,892 ($55.61 per hour multiplied by 1,065 hours) in order to comply with this additional QIP submission requirement. We are seeking to revise our collection approved under OCN 0938–1023 to account for this new requirement for certain D–SNPs participating in this benefits flexibility initiative.

L. ICRs Regarding Clarifying Payment to Providers in Instances of Hospital-Acquired Conditions (HACs) (§ 422.504)

We proposed to require MA organizations provide in their contracts with hospitals that payments for Part A hospital services will be reduced for serious events that could be prevented through evidence based guidelines, in accordance with the HACs and POA policy that is currently required for hospitals paid under the Original Medicare IPPS. We believe that plans already have some operational systems in place to facilitate implementation of the requirement. For example, MA organizations are already required to pay non-contract provider hospitals the amount that they will receive for services under original Medicare, including any applicable reductions for HACs. Also, beginning January 3, 2012, MA plans will be required to collect and submit encounter data for each item and service provided to MA enrollees in accordance with risk adjustment policies required in § 422.310(d). This information is collected using the HIPAA 5010, which is already in use by hospital providers for FFS claims and contains fields for POA indicator reporting. While this requirement is subject to the PRA, the diagnosis, POA indicator information, and other claims information is already collected as part of the encounter data collection process, and this burden is currently approved under OCN 0938–1054.

Additionally, we expressed our belief that hospitals will already be familiar with POA reporting and will not require additional education. Therefore, the burden associated with this provision would be the time and effort necessary for MA plans to modify their claims processing to recognize the POA indicators, if they do not already do so, and to adjust payment to contracted hospitals for the HAC events accordingly. Plans usually update their claims processing systems regularly for changes such as, payment logic for new national and local coverage determinations, updating HCPCS code information, and other changes to their payment calculations. Therefore, we believe this burden is exempt from the PRA as defined in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this requirement will be incurred by plans in the normal course of their business activities.

We received no comments on the information collection requirements associated with this proposal. However, based on the comments received on the proposed policy, we are not finalizing this proposal. We will continue to not only consider alternate strategies for reducing hospital-acquired conditions in hospitals that provide care to MA enrollees, but also strive toward aligning quality initiatives in the Medicare and Medicare Advantage programs.

M. ICRs Regarding Clarifying Coverage of Durable Medical Equipment (§ 422.101(a) and § 422.112(a))

Under § 422.100(l), we proposed to permit MA plans to limit coverage of DME to specific manufacturers' products or brands. Furthermore, in order to ensure that MA enrollees have adequate access to their DME benefits, our proposed regulatory changes establish requirements with respect to access, midyear changes to preferred DME items and supplies, appeals, and disclosure of DME coverage limitations to enrollees. The burden associated with this requirement is the time and effort necessary for MA organizations to submit their benefit designs via the PBP software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938–0763. With respect to disclosing DME coverage limitations, this requirement is captured in the burden associated with the annual notice of coverage/evidence of coverage which must be completed at the time of the beneficiary's enrollment and at least annually thereafter. The MA program disclosure requirement is at § 422.111 and the burden associated with it was formerly approved under OCN 0938–0753 which expired November 30, 2011. We are seeking to reinstate this collection in order to account for the new DME disclosure requirement.

N. ICRs Regarding Broker and Agent Requirements (§ 422.2274 and § 423.2274)

At § 422.2274 and § 423.2274, we proposed that plans can choose any agent/broker compensation amount at or below the fair market value amount annually. We require MA organizations to submit and/or update and attest to their compensation amount (or range) in the HPMS. This web-based system in HPMS allows new plans to submit information and, for existing plans, automatically updates, based on changes in MA payment rates, organization compensation information. We proposed to allow plans to annually adjust their base compensation rates to reflect fair market value. Plans would continue to be required to annually submit and attest to this information to CMS through HPMS. While this proposed requirement is subject to the PRA, it does not impose any new information collection requirement on plans. The burden associated with the proposed requirement was formerly approved under OMB control number (OCN) 0938–0753 which expired November 30, 2011. We are seeking to reinstate this collection.

O. ICRs Regarding the Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.100, § 423.104 and § 423.153)

In accordance with section 1860D–4(c) of the Act, we are revising § 423.153 at paragraph (b)(4) to provide that a Medicare Part D sponsor's drug utilization management program must establish and apply a daily cost-sharing rate, under certain circumstances, to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days. Under this requirement, the enrollee and his or her prescriber generally will decide if a medication supply of less than 30 days will be appropriate, and if so, the cost-sharing for the medication will be prorated by the Part D sponsor based on the days supply dispensed. Since obtaining a supply of a medication for less than 30 days is optional for the enrollee and his or her prescriber, the collection of information burden imposed by these regulations on either Part Medicare D enrollees or their prescribers is negligible. Moreover, any burden associated with this proposal on sponsors related to the required data entry in the PBP software will be included in the revised PRA package entitled Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) for Contract Year (CY) 2014, since we are delaying the effective date of this requirement until January 1, 2014.

After consideration of the public comments received, none of which specifically addressed this collection of information burden section, we are modifying this requirement as discussed in section II.D.6. of this final rule with comment period (Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.100, § 423.104 and § 423.153)). However, we are not modifying these ICRs, since the collection of information burden imposed by this final rule with comment period will still be negligible, and any burden associated with it will still be captured elsewhere.

P. ICRs Regarding Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)

At § 417.422, § 417.432, § 422.60, and § 423.56 we are proposed technical changes that correct cross-references that should have been updated in previous rulemaking. These changes do not establish any new rules or requirements for cost or Part D plans. They merely update regulatory cross-references that were overlooked in previous rulemaking. As a result, these changes do not impose any new information collection requirements.

Q. ICRs Regarding Applying MA and Part D Disclosure Requirements to Cost Contract Plans (§ 417.427)

We proposed to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans. Our regulations at § 422.111 and § 423.128 require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/ evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. Sections 422.111 and § 423.128 also require the provision of certain information about requests and establish requirements with respect to dissemination of explanations of benefits, customer service call centers, and Internet Web sites.

The burden associated with this requirement is the time and effort associated with completing an ANOC/ EOC at the time of a beneficiary's enrollment and at least annually thereafter, as specified in § 422.111(a)(2) of the MA program regulations and § 423.128(a)(3) of the Part D program regulations. For each entity, we estimate that it will take 12 hours to develop and submit the required information. This includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, 4 hours to print and disclose to the beneficiaries. This package is currently approved under OCN 0938–0753 with a November 30, 2011 expiration date to account for this burden as detailed in Table 7. We estimate 20 cost contractors would be affected annually by this requirement, resulting in a total annual burden of 240 hours. We estimate, based on an hourly wage of $29.88 (hourly salary for a compliance officer/cost estimator according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead, that this requirement will result in a total annual burden of $10,613 (240 burden hours multiplied by $44.22 per hour). We are revising the PRA package currently approved under OCN 0938–0753 with a November 30, 2011 expiration date.

R. ICRs Regarding Clarification of and Extension of Regional Preferred Provider Organization Plan Single Deductible Requirements to Local Preferred Provider Plans (§ 422.101)

This section does not impose any new information collection requirements.

S. ICRs Regarding Modifying the Current PFFS Plan Explanation of Benefits (EOB) Requirements (§ 422.216(d)(1))

Section 1852(k)(2)(c) of the Act and § 422.216(d)(1) require PFFS plans to provide an EOB to enrollees for each claim filed by the enrollee or the provider that furnished the service. In the interest of consistency for beneficiaries and MA organizations, we proposed to amend § 422.216(d)(1) to state that the EOB requirement for PFFS plans would be consistent with the MA EOB requirements of § 422.111(b)(12). The standard EOB that we are currently developing and piloting in CY 2012 for most other MA plan types would include the same information as currently required for PFFS plans, as well as plan MOOP cost limit information. Adding this cross-reference to § 422.216(d)(1) would provide consistency in EOB requirements and submission and approval of marketing materials across plan types. Since the pilot program is in progress and we would not have finalized EOB requirements during this rulemaking, we proposed that PFFS plans would continue to furnish EOBs as they have been, in accordance with § 422.216(d)(1), until we finalize and implement EOB models for all MA plans. While this proposed requirement is subject to the PRA, the information collection has been approved under CMS form CMS–10349, the information collection approved for the Part C EOB at § 422.111(b)(12).

T. ICRs Regarding Authority To Deny SNP Applications and SNPs Appeal Rights (§ 422.500)

Our proposed amendments to § 422.500(a), § 422.501(a), § 422.501(c)(1)(iii), § 422.502(a) and § 422.502(c) would give CMS the authority to deny SNP applications that fail to demonstrate that the MA organization meets the requirements of § 422.2, § 422.4(a)(1)(iv); § 422.101(f); § 422.107, if applicable; and § 422.152(g). The burden associated with this requirement is the time and effort required by an MA organization offering a SNP to complete a SNP application. While these requirements are subject to the PRA, we do not expect the burden to change from the existing burden estimate, as currently approved under OCN 0938–0935, with a January 31, 2012 expiration date. We are seeking to renew this collection.

Our proposed amendments to § 422.641 provide the procedures for making and reviewing certain contract determinations, while our proposed amendments to § 422.660 establish the circumstances under which an MA organization may request a hearing before a CMS hearing officer. We proposed these amendments to our existing regulations so that each applicant that we determine not to be qualified to offer a SNP has the right to request an administrative review of CMS' determination. The burden associated with these requirements is the time and effort of the SNP applicant in developing and presenting their case to a CMS hearing official, and ultimately the CMS Administrator, to demonstrate that they qualify to offer a SNP.

We expect the burden associated with this provision to be incurred by the small number of SNP applicants that we expect would receive application denials, and the small percentage of denied applicants that we expect would appeal our denial decision. We estimate that the total annual hourly burden for developing and presenting a case for us to review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing SNP to research, draft, submit, and present their arguments to CMS. Based on SNP application denials from contract year 2012, out of the approximately 400 SNP applications received, 8 of these applications were denied and all 8 denials were appealed. In contract year 2011, 8 SNP applications were denied and none of these denials were appealed. Taking the average of the last 2 years, we estimate that approximately 4 denied applicants would appeal the denial of the SNP application. We further estimate that one attorney working for 8 hours could complete the documentation to be submitted for each application denial, resulting in a total burden estimate of 32 hours (8 hours × 4 SNP application denials = 32 hours). The estimated annual cost to all MA organizations, in the aggregate, that have been denied to offer a SNP associated with this provision (assuming an attorney billing $250 per hour) is $8,000 (32 hours × $250 = $8,000) as detailed in Table 7. We are revising the PRA package currently approved under OCN 0938–0935, with a January 31, 2012 expiration date, to account for this burden. We are seeking to renew this collection.

U. ICRs Regarding Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)

This section does not impose any new information collection requirements.

V. ICRs Regarding Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)

We proposed to modify the regulations at § 422.504(i) and § 423.505(i) by deleting the term ''written arrangements'' throughout and in each instance replacing it with ''each and every contract,'' thus ensuring that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities by requiring that all contracts among those entities specifically reference their obligations to the sponsor.

Regarding ICRs, we are not imposing any new reporting requirements. We are simply clarifying a requirement with which MA organizations and Part D sponsors must already comply concerning their contracts with first tier and downstream entities. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

W. ICRs Regarding Valid Prescriptions (§ 423.100 and § 423.104)

Our proposed definition of ''valid prescription'' in § 423.100 and requirement of a ''valid prescription'' in § 423.104 would codify our longstanding policy of deferring to State laws when applicable to determine whether a prescription is valid such that the drug may be eligible for Part D coverage. We are not imposing any new reporting requirements. Prescribers and pharmacies remain subject to applicable State laws regarding valid prescriptions. Furthermore, private contracts regarding Part D drugs (such as those between MA organizations or Part D sponsors and pharmacies) likely also require valid prescriptions. Given these realities, we do not believe that codifying our practice of limiting Part D coverage to items dispensed upon applicable State law requirements for valid prescriptions could necessitate any more action than that already required on the part of stakeholders—be they prescribers taking steps to ensure they write valid prescriptions or MA organizations, Part D sponsors, PBMs, or pharmacies trying to ascertain that prescriptions are valid.

X. ICRs Regarding Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

Current regulations require that unless a beneficiary is in a LTC setting, the comprehensive medication review (CMR) must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. Section 10328 of the Affordable Care Act amended section 1860D–4(c)(2) of the Act to require that all targeted beneficiaries be offered a CMR. Accordingly, we proposed a change to § 423.153 permitting the sponsor to allow the pharmacist or other qualified provider to perform the CMR without the beneficiary in cases when the beneficiary is in a LTC facility and is cognitively impaired and thus, cannot accept the sponsor's offer of a CMR . We anticipated that the impact of this proposed revision would clarify the CMR process for sponsors by allowing pharmacists and other qualified providers to ascertain whether the patient is willing and able to participate in a CMR before administering it.

We incorrectly stated in the proposed rule that we did not anticipate any costs or savings associated with this change. However, there will be a modest increase in costs based on the requirement to offer CMRs to beneficiaries residing in LTC settings with written summaries and provide the summaries and action plans for these beneficiaries in a standardized format that complies with the requirements specified by CMS. We estimate that 215,000 beneficiaries in LTC settings are eligible for MTM services and 10 percent (21,500) of those beneficiaries will receive an annual CMR. We also estimate that the average CMR requires 35 minutes to complete and the average hourly compensation (including fringe benefits, overhead, general and administrative expenses and fee) of the MTM provider is $120. Therefore, the estimated total annual cost of providing CMRs in LTC settings is $1,504,140 (21,500 CMRs × 0.583 hours/CMR × $120/hour). The estimate reflects costs previously calculated in the OCN 0938–1154.

Y. ICRs Regarding Coordination of Part D Plans With Other Prescription Drug Coverage (§ 423.458)

We proposed a change to simply strengthen our policy regarding EGWP sponsor responsibilities, there is no additional burden on the part of sponsors or other entities associated with the regulation. This section does not impose any new information collection.

Z. ICRs Regarding Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

The inconsistent use of identifiers that have not been validated has hindered efforts to combat fraud and abuse. Therefore, we will require, effective January 1, 2013, that Part D sponsors must include active and valid individual prescriber NPIs as identifiers in PDEs submitted to CMS. Since Part D sponsors are already required to include a prescriber identifier on PDEs submitted to CMS, there is no new collection of information burden imposed by this proposed regulation. Furthermore, the change does not impose any new collection of information burden on Medicare beneficiaries enrolled in the Part D program with respect to requests for reimbursement they may submit, since the requirement is imposed on Part D sponsors. After consideration of the public comments received, none of which specifically addressed this collection of information burden section, we are modifying this requirement as discussed in section II.E.11. of this final rule with comment period, Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120). However, we are not modifying these ICRs since, again, no new collection of information burden is imposed by this requirement.

TABLE 7—ESTIMATED FISCAL YEAR REPORTING, RECORDKEEPING AND COST BURDENS

Regulation sections	OMB control No.	Respond-ents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost ($)	Total capital/ mainte-nance costs ($)	Total cost ($)
417.427	0938–0753	20	20	12	240	44.22	10,613	N/A	10,613
422.102	0938–1023	73	73	15	1,095	55.61	60,893	N/A	60,893
422.500	0938–0935	4	4	8	32	250.00	8,000	N/A	8,000
423.153	....	21,500	21,500	0.583	12,534.5	120.00	1,504,140	N/A	1,504,140
Total	....	21,597	21,597	....	13,901.5	....	....	N/A	1,583,646

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

AA. Additional Information Collection Requirements—Independence of LTC Consultant Pharmacists

In the proposed rule we imposed collection of information requirements as outlined in the regulation text and specified earlier in this section. However, we also made reference to associated information collection requirements that were not presented in the regulation text of the proposed rule. In our October 11, 2011 proposed rule (76 FR 63067), we discussed the information collection requirements related to the changes we considered that would require each LTC facility to employ or obtain the services of a consultant pharmacist who was not employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

Comment: Many commenters noted that the services performed by LTC consultant pharmacists are more extensive than the drug regimen reviews and include activities such as destroying unused medications, checking storage areas, conducting exit conferences, providing in-service education to nursing staff, observing medication distribution, and attending meetings. Commenters stated the full range of consultant pharmacist services need to be considered in determining the burden associated with the new requirements.

Response: We appreciate these comments and will use them to inform possible future rulemaking regarding the LTC consultant pharmacist requirements. However, after considering the public comments received, we are not finalizing this provision at this time.

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final rule with comment period is to make revisions to the MA Part C and Part D programs to implement provisions specified in the statute and make other changes to the regulations based on our continued experience in the administration of the Parts C and Part D programs. The final rule with comment period will—(1) Implement statutory provisions; (2) strengthen beneficiary protections; (3) exclude plan participants that perform poorly; (4) improve program efficiencies; and (5) clarify program requirements.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule with comment period has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered by proposed requirement. Details regarding the burden associated with the requirements of this final regulation are located in the Collection of Information section (section IV. of this final rule with comment period).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.0 million to $34.5 million in any 1 year). Individuals and States are not included in the definition of a small entity. This final rule does not directly impact, health care providers, suppliers and State governments since it amends the current requirements for MA organizations and Parts D sponsors, and adds requirements for pharmaceutical manufacturers consistent with the statutory requirements of the new manufacturer drug discount program. Part D sponsors and pharmaceutical manufacturers, the entities that will largely be affected by the provisions of this rule, are not generally considered small business entities. Part D sponsors must meet minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. We determined that there were very few Part D sponsors that fell below the size thresholds for ''small'' businesses established by the Small Business Administration (SBA). Currently, the SBA size threshold is $7 million in total annual receipts for health insurers (North American

Industry Classification System, or NAICS, Code 524114) and CMS has confirmed that most Part D sponsors have Part D receipts above the $7 million threshold. We also determined that there were very few pharmaceutical manufacturers participating in the Medicare prescription program drug discount program that fell below the size thresholds for small businesses using the SBA size threshold of 750 employees (NAICS code 32541). Total jobs data for manufacturers support the fact that the pharmaceutical industry is dominated by large businesses.

While the NAICS lists 1,555 business in the United States that represent the pharmaceutical and medicine manufacturing industry only 237 brand manufacturers currently participate in the program, and most exceed the 750 employee threshold. The majority of smaller manufacturers are either generic or specialty pharmaceutical manufacturers that are unlikely to participate in the Medicare discount program. We reviewed some of the employment statistics for the smaller specialty pharmaceutical manufacturers that participate in the discount program, and found that the number of employees typically exceeds the SBA threshold.

While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. Similarly, manufacturers are not normally considered small business entities. However, there are manufacturers that have minimal revenue, primarily because their emphasis is on the development of products rather than sales or they are not focused on large markets. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because this final rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule with comment period will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold was approximately $136 million. This final rule with comment period is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this final rule with comment period imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

After considering the public comments received, we are not finalizing two of the provisions included in the proposed rule—Application of Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA organizations, and Independence of LTC Consultant Pharmacists. We estimated that the impact of the former provision would be negligible and received no comments on our estimate. We estimated the costs and savings associated with the consultant pharmacist independence provision and stated that we believed the costs and benefits would be offsetting. Some commenters disagreed with our estimates. However, we agree with the many commenters who claimed that the requirement for consultant pharmacists to be independent would be highly disruptive to the industry, but would not solve drug overutilization and inappropriate prescribing in LTC, because others, such as LTC facility staff and physicians, contribute significantly to the problem. Therefore, although we believe changes are necessary and a requirement for consultant pharmacist independence is part of the right approach, we are not finalizing the requirement in this rule. Since we are not finalizing these two provisions, they have no impact on this final rule with comment period.

In Table 8, we estimate total costs to the Federal government, States, Part D sponsors, MA organizations, pharmaceutical manufacturers and other private sector entities as a result of various provisions of this final rule with comment period. The provisions with the most significant costs (costs greater than $100 million from FY 2013 through FY 2018) in this final rule with comment period are the Medicare Coverage Gap Discount Program (Discount Program), and the Inclusion of Benzodiazepines, and Barbiturates as Covered Part D drugs.

The total costs of the Discount Program for the periods beginning FY 2013 through FY 2018 are estimated to be $31.1 billion, and the total costs of the inclusion of benzodiazepines and barbiturates is $1.9 billion.

Tables 9, 10, and 11 detail the costs by cost-bearing entity. Specifically, Table 9 describes costs and savings to the Federal government, Table 10 describes costs to MA organizations and/or PDP sponsors and third party entities, Table 11 describes costs to pharmaceutical manufacturers, and Table 12 describes savings to States.

As a result, when considering both the costs and savings associated with the provisions of this final rule with comment period, we conclude with a net cost estimate of $31.3 billion for FY 2013 through FY 2018.

C. Anticipated Effects

1. Medicare Coverage Gap Discount Program

The Discount Program makes manufacturer discounts available at the point-of-sale to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. In general, the discount on each applicable drug is 50 percent of an amount equal to the negotiated price of the drug (less any dispensing fee). In general, manufacturers must agree to provide these discounts by signing an agreement with CMS in order for their applicable drugs to continue to be covered under Medicare Part D.

a. Required Payment of Gap Discounts

We believe that there will be significant costs to manufacturers from paying the required discounts to beneficiaries while in the coverage gap. We estimate that aggregate discounts from pharmaceutical manufacturers will be $29.7 billion during FY 2013 through

FY 2018. That estimate is based upon historical patterns of claims dispensed during the coverage gap and the dollar amount of those claims trended forward by enrollment growth and price increase.

In addition, the Discount Program will increase Medicare costs by inducing additional use of more expensive brand name drugs by improving beneficiary adherence as a result of the lower out-of-pocket costs by increasing use of brand name instead of generic drugs. The increased use of brand name drugs will increase Medicare costs by increasing the number of beneficiaries reaching the Part D catastrophic threshold and thereby, increasing the cost of plan benefits. We estimate that the Discount Program will increase Medicare costs by $1.3 billion during FY 2013 through FY 2018.

It is important to note that these estimated Medicare costs do not include costs related to the Affordable Care Act provisions that revised the Part D benefit structure to close the coverage gap. These provisions not only revised the coinsurance amount, but also reduced the growth in the annual out-of-pocket threshold. The costs to the Federal government associated with these provisions, as scored in the April 15, 2011 final rule (76 FR 21432), were estimated to total $3.6 billion during FY 2011 through FY 2016.

b. Other Manufacturer Costs

We believe that manufacturers will also incur costs as a result of specific obligations under the Discount Program Agreement. The Discount Program Agreement must be signed by all participating manufacturers and provides the terms and conditions for timely payment of discounts, disputes and appeals, penalties, and termination of the Agreement. In order to comply with the Discount Program Agreement, manufacturers will need to analyze and pay quarterly invoices, notify CMS about labeler code changes, notify FDA about NDC changes and maintain records for potential audit by CMS. This will require them to establish connectivity with the Discount Program third party administrator (TPA) to receive quarterly invoices and file disputes, and obtain access to the CMS Health Plan Management System (HPMS) to update and maintain contact and labeler code information. However, manufacturers already have existing systems and perform similar activities as a result of their experience with Medicaid and Tricare. We estimate that analyzing and paying the quarterly invoices will require 0.5 FTEs. We estimate that the cost to manufacturers will be $73,380 (annual salary for a Pharmaceutical Manufacturing Compliance Officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead × 0.5 FTE × 240 manufacturers × 6 years for a total cost of $78.2 million over the complete period FY 2013 through FY 2018.

2. Payment Processes for Part D Sponsors

We believe that there will be a minor impact on Part D sponsors from receiving and reconciling estimated rebates advanced by CMS with subsequent payments by manufacturers. Part D sponsors have experience and existing systems to accept and reconcile funds with CMS, including a LICS subsidy and a reinsurance subsidy. We believe that there will be a marginal increase in resources focused on accounting and computer system operations and maintenance. We estimate that the additional resources required will be 0.5 FTEs, on average, per Part D sponsor. We estimate that the total cost to Part D sponsors will be $63,360 (annual salary for insurance carrier compliance officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead × 0.5 FTE per Part D sponsor × 270 Part D sponsors × 6 years for a total of $76.0 million over the complete period FY 2013 through FY 2018.

3. Provision of Applicable Discounts for Applicable Drugs for Applicable Beneficiaries

We believe that there will be a minor impact on Part D sponsors as a result of this provision. Part D sponsors already implement systems to adjudicate pharmacy claims. With the exception of calculating and accounting for gap discounts, those systems include similar, if not identical, tasks as the requirements in the final rule. Further, we believe that the carrying cost of distributing the discounts to beneficiaries will be offset by prospective payments from us as previously described.

We believe that the additional workload associated with this final regulation will involve modifications to existing computer programming to account for the differences between the Discount-related systems and the traditional Part D program. In addition, we expect there to be additional reporting and recordkeeping. We estimate that Part D sponsors will increase resources the equivalent of 0.5 additional FTEs to accomplish these tasks. We estimate the cost to Part D sponsors will be $63,360 (annual salary for insurance carrier compliance officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead × 270 Part D sponsors × 6 years for a total cost of $76.0 million over the complete period FY 2013 through FY 2018.

4. Manufacturer Discount Payment Audits and Dispute Resolution

The final regulation will permit manufacturers to undertake audits of the data used to calculate quarterly invoices and to dispute the invoices themselves. We believe that the activities necessary for disputing invoices and conducting data audits will be accommodated by the additional resources that we earlier linked to the Discount Program Agreement. Therefore, we are not estimating an additional economic impact to manufacturers from this provision.

5. Beneficiary Dispute Resolution

The final rule will create the right of beneficiaries to dispute gap discounts using preexisting Part D sponsor beneficiary dispute resolution mechanisms. We believe that the potential increase in beneficiary dispute volume will not require additional Part D sponsor resources. We have made significant efforts to ensure that the data used to calculate the discounts are accurate. We believe that the accuracy of the data, coupled with the automation of the dispute calculation, will result in accurate discounts that will generate few beneficiary appeals and will be accommodated within existing resources.

6. Compliance Monitoring and Civil Money Penalties

The final regulations require CMS to impose penalties if a manufacturer does not pay gap discounts that are owed according to the terms of the Discount Program Agreement. We believe that, in general, manufacturers will pay the quarterly invoice according to the terms within the Discount Program Agreement and, therefore; we expect very few instances where manufacturers are levied a civil money penalty. Accordingly, we assume that monetary penalties will be levied on only a very small percent of all discount payments, estimated to be approximately 0.03 percent, for a total of $9.64 million in civil money penalties imposed over the period FY 2013 through FY 2018.

7. Termination of Discount Program Agreement for Part D Program

We believe that we will rarely find it necessary to terminate an agreement. Upon termination, covered Part D drugs of the manufacturers will be excluded from the Part D program and the manufacturer potentially will suffer a significant reduction in revenue. We have experience with similar programs and believe that the potential reduction of revenue will encourage manufacturers to resolve our concerns. This will tend to avoid terminations and the associated fiscal effects. Consequently, we estimate that there will be no material costs to manufacturers due to potential agreement terminations during the period FY 2013 through FY 2018.

8. Inclusion of Benzodiazepines and Barbiturates as Part D Drugs

In accordance with section 175 of the MIPPA that amended section 1860D–2(e)(2)(A) of the Act (42 U.S.C. 1395w–102(e)(2)(A)),we proposed to revise the definition of Part D drug at § 423.100, by including barbiturates when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines class drugs as covered under Part D effective January 1, 2013.

Under this provision, Part D plan sponsors will be required to submit information in their formulary files indicating that they will cover these drugs. We estimated that the cost to the Federal Government to be $1.9 billion over the 2013 through 2018 period. We assumed the cost of benzodiazepines and barbiturates as 0.4 percent of total drug cost, and that the inclusion of both these drugs will increase proportional to the current overall Part D level.

9. Good Cause and Reinstatement Into a Cost Plan

At § 417.460(c)(3) we proposed to allow beneficiaries who have been disenrolled from their cost plans for nonpayment of premium or other charges imposed by the plan for deductible and coinsurance amounts the opportunity to be reinstated into their plan if they can establish good cause for nonpayment of cost-sharing. CMS (or its designee) will evaluate cost-plan enrollees' requests for reinstatement based on good cause and make the ''good cause'' determinations. We anticipate that there would be no cost impact on cost plans. We received no comments on the regulatory impact analysis of this proposal and therefore are finalizing this provision without modification.

10. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

We are clarifying our regulations at § 423.56 to define creditable prescription drug coverage consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d). Since this is a clarification to an existing calculation that is already being utilized by organizations providing creditable coverage, there will be no cost impact on these organizations.

We received no comments on the regulatory impact analysis of this proposal and are finalizing this provision without modification.

11. Who May File Part D Appeals With the Independent Review Entity

The changes to § 423.600 will allow prescribing physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees and the corresponding change to § 423.602(a) specifies that the IRE must also notify the prescribing physician or other prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The quantifiable burden associated with these provisions is the cost of processing Part D reconsiderations (which includes providing notice of the decision). While this provision is expected to increase the number of reconsiderations processed and completed by the IRE, it will also significantly reduce the number of appeals that have to be dismissed because the AOR form would no longer be required in cases when a prescriber is requesting a reconsideration on behalf of an enrollee. In 2010, the IRE dismissed approximately 2,500 reconsideration requests submitted by prescribers due to the lack of a properly executed AOR form, at an estimated cost of $215,000. We estimate the cost of issuing a substantive reconsideration decision in cases that are currently subject to dismissal to be $540,000, assuming an estimated cost of about $216 per case. However, this added cost would be offset by the reduction in dismissed cases, for an estimated annual cost increase of $325,000 ($540,000 less $215,000).

We also believe that eliminating the AOR requirement will result in about a 15 percent increase in the total number of IRE reconsiderations requests. Based on the percentage of plan level appeals currently filed by prescribers on behalf of enrollees (approximately 85 percent), we estimate an increase in prescriber-initiated IRE appeals, which would be partially offset by a decrease in enrollee-initiated IRE appeals. Based on 2010 reconsideration data, we estimate there would be an additional 3,000 reconsideration requests, with an estimated increase in annual costs of about $648,000. The estimated increased cost associated with issuing substantive reconsideration decisions (as opposed to dismissals) and the increased cost associated with the increase in the reconsideration workload, results in total estimated annual increased costs to the Federal government of approximately $973,000 or a total of $5.84 million for FYs 2013 through 2018.

The increase in reconsideration requests would result in additional costs to plan sponsors based upon additional time and effort to assemble case files and documentation associated with these requests and shipping to the IRE for processing. We assume a cost of approximately $25.00 per reconsideration to print, copy, compile, and mail the case file to the IRE. This results in an additional annual cost to all Part D plan sponsors of approximately $75,000 ($25 per file × 3,000 additional files = $75,000), or a total of $450,000 from FYs 2013 through 2018.

Comment: CMS received a few comments on the regulatory impact analysis of this proposal. A commenter, citing the greater number of IRE reconsideration requests under the MA program and linking that in part to providers' ability to initiate appeals, urged CMS to consider additional administrative costs associated with this change. Another commenter specifically noted the increased burden placed on plan sponsors' appeals departments as a result of having to prepare a larger number of case files for the IRE.

Response: We agree that compared to the Part D program, the MA program has a significantly higher number of IRE appeal requests. However, this is not a result of provider appeals, because in the MA program, providers do not technically have a right to appeal an adverse plan reconsideration to the IRE. Instead, in MA, all adverse plan reconsiderations are auto-forwarded to the IRE for review. We are not proposing that all adverse redeterminations in the Part D program be auto-forwarded to the IRE. The burden estimate already includes a discussion of the burden associated with the increased number of reconsiderations as a result of the proposed change and the increased number of cases that plan sponsors will need to prepare for shipment to the IRE. Thus, we believe that we have accurately accounted for the estimated burden increase related to this provision, both for the government and plan sponsors, and are finalizing this provision without modification.

12. Termination for Continued Lower-Than-3-Star-Ratings

We have the authority under section 1857(c)(2) of the Act to terminate contracts with a MA organization or a Medicare PDP sponsor when we determine that the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the Part C or D program. We believe that a sponsor that fails to achieve at least a 3-star rating for 3 consecutive years has demonstrated consistently that it is unable or unwilling to take corrective action to improve its Part C or D performance. Therefore, we are proposing to revise the regulation to reflect our position that 3 years' worth of low star ratings constitutes a sufficient basis for CMS to terminate a sponsor's Part C or D contract.

The changes made to this regulation will not result in any additional costs. MA organizations and Part D sponsors already incur costs as a result of needing to be in compliance with existing regulatory requirements. This change merely clarifies our authority to use sustained poor performance rating results (which are already being produced annually) as a basis for termination.

13. Exclusion for Sponsors of Contracts Terminated for Cause

We have modified the past performance review period described in § 422.502(b) and § 423.503(b) (by adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) as well as § 422.502(b)(4) and at § 423.503(b)(4)) to include among the factors that may support a CMS denial of a contract application those CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application.

The changes made to this regulation will not result in any additional costs since we are not imposing any new requirements. Rather, we are merely extending the period of time that we can review for purposes of application qualification determinations when an organization has had a prior contract terminated or non-renewed by CMS. Thus, there are no additional costs involved.

14. Independence of Long Term Care Consultant Pharmacists

In our October 11, 2011 proposed rule (76 FR 63071), we discussed the anticipated effects of the changes we considered that would require each LTC facility to employ or obtain the services of a consultant pharmacist who was not employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

Comment: Some commenters disagreed with our belief that the costs and benefits associated with this provision would be offsetting. Instead, they contended that the requirement for independent consultant pharmacists would create a financial burden for facilities and consultant pharmacists and that the requirement would cost, not save, money.

Response: We are not finalizing the requirement for consultant pharmacists to be independent in this rule. However, we appreciate the comments on our impact analysis and will consider the information provided in the process of possible future rulemaking on this issue.

15. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D–SNPs) (§ 422.102)

We estimate that our modification of § 422.102(e) to allow certain D–SNPs to offer additional supplemental benefits beyond those other MA plans—subject to CMS approval, and as specified annually by CMS—will result in aggregate savings to both States and the Federal government of approximately $137.7 million between FY 2013 and FY 2018. These Federal and State savings estimates are based on our assumption that, based on the eligibility standards we establish, approximately 73 D–SNPs will qualify to participate in this initiative, representing a total of approximately 507,000 enrollees in 2011. We estimate that D–SNPs participating in this initiative will incur a small cost of approximately $0.07 million annually in order to comply with the QIP reporting requirements that we are requiring for eligible D–SNPs as a condition of participating in this initiative. Accounting for these administrative costs to MA organizations, we estimate this provision will result in an aggregate savings to the health care sector of $137.22 million between FY 2013 and FY 2018.

While we acknowledge that the current authority for all SNPs, including D–SNPs, to restrict enrollment to special needs individuals (under section 1859(f)(1) of the Act), expires at the end of the 2013 contract year, we report the impact of this provision from FYs 2013 through 2018, to be consistent with the scoring of other provisions of this rule. We note that this impact may vary based on Congressional action.

We are basing our analysis of the potential cost impacts of the D–SNP benefit flexibility initiative on our experience with HMO integrated care model demonstrations for Medicare-Medicaid dual eligibles and on our observation of enrollment increases that resulted from these demonstrations.

From 1997 through 2006, we conducted demonstrations that pooled Medicare and Medicaid payments to the Minnesota Senior Health Options (MSHO), Wisconsin Health Partnership Program (WPP) and Massachusetts Senior Care Organization (MSCO) HMOs to deliver Medicare and Medicaid-covered primary, acute, and long-term care services to voluntarily enrolled elderly dual eligibles. The plans participating in the demonstration were responsible for delivering Medicaid community care services, developing managed care coordination models, and arranging for the delivery of the full range of acute and long-term care services and developing care coordination models—characteristics that we believe are essential for the provision of comprehensive, integrated care. The demonstrations also used Medicaid funds to cover community care services (for example, personal care, homemaking, transportation, personal emergency response systems, home-delivered meals, adaptive equipment, home modifications, incontinence supplies, and respite care that support independence and avoid inappropriate institutionalization). At the start of the demonstrations, concern that marketing additional supplemental benefit offerings would attract a significant number of new enrollees-led us to cap enrollment in the demonstration. However, States in the demonstration never came close to reaching this enrollment cap. The only major enrollment increase was in 2006, when the demonstration programs were converted to D–SNPs, and the D–SNPs were able to passively enroll enrollees.

The MSHO demonstration, the most extensively analyzed integrated care demonstration program for dual eligible enrollees, received a Medicare and a Medicaid capitation payment for the provision of acute and long-term care services, but reimbursed providers directly for nursing home services on a fee-for-service basis. Therefore, Federal and State government costs under this capitated program were not related to actual utilization, with the exception of fee-for-service nursing home costs. Utilization data from the MSHO demonstration show that MSHO enrollees had significantly fewer short-stay nursing home admissions as compared to dual eligibles both within and outside of the MSHO demonstration area.

We believe that plans have incentives to generate higher rebates to fund these extra supplemental benefits and have assumed that they will reduce their margins by 1 percent. Taking into account expected growth rates in bids and benchmarks, and projected rebate shares, we expect that D–SNPs that participate in this benefit flexibility initiative will reduce their bids by 2 percent on average—1 percent medical and 1 percent margin—as a result of our proposed changes to § 422.102(e). Applying the per-capita savings to the projected enrollment for these qualified D–SNPs, we project $131.6 million savings to the Medicare program for the 6-year period between FY 2013 and FY 2018.

We also believe that, when delivered in a prudent manner, the additional benefits that qualified D–SNPs will be permitted to offer under our proposed changes to § 422.102(e) will allow some high-risk patients to remain in their home and out of institutions. We estimate that the new flexibility will generate modest reductions in Medicare program expenditures, due to a 1 percent savings of Medicare-covered medical benefits stemming from these enhanced flexibilities.

Additionally, based on the evidence from the studies in Massachusetts, Minnesota, and Wisconsin demonstrations, we believe that the flexibility for D–SNPs to offer additional supplemental benefits will modestly impact nursing facility utilization rates and Medicaid costs. Our assumptions regarding the effectiveness of these services in preventing nursing facility entry are consistent with assumptions we have used for other legislative and regulatory proposals aimed at reducing nursing facility use and encouraging home and community based long term care. Applying the per-capita savings to the projected enrollment for D–SNPs that would qualify to participate in this initiative, we estimate Federal and State Medicaid savings of $6.12 million for the 6-year period between FY 2013 and FY 2018 as a result of this provision.

Finally, as detailed in the section III. Information Collection Requirements, of this final rule with comment period, we estimate an annual cost of $60,893 to MA organizations as a result of this provision's requirements. This cost reflects the administrative cost, including burden hours and staff wage rates, that participating D–SNPs would incur in order to complete and submit the additional QIP that we are requiring as a condition of participating in this benefits flexibility initiative. We estimate that these requirements will cost MA organizations approximately $0.36 million from FYs 2013 through 2018.

16. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

We proposed to require MA organizations to reduce reimbursements for Part A hospital services for contract provider hospitals for serious events that could be prevented through evidence based guidelines, in accordance with the HACs and POA policy that is currently required for hospitals paid under the Original Medicare IPPS. MA organizations are already required to pay non-contract provider hospitals the amount that they will receive for services under Original Medicare, including any applicable reductions for HACs. This requirement is outlined in the MA Payment Guide for Out of Network Payments.

Based on the comments received, we are not finalizing this proposal, but will continue to consider alternate strategies for reducing hospital-acquired conditions in hospitals that provide care to MA enrollees and strive toward aligning quality initiatives in the Medicare and Medicare Advantage programs.

17. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

As discussed in section II.D.6. of this final rule with comment period, Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program, a previous review of 2009 PDE data suggested that the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was roughly $1.4 billion. In light of this cost, we proposed to revise § 423.153(b)(4) to provide that a Medicare Part D sponsor's drug utilization management program must establish and apply a daily cost-sharing rate, under certain circumstances, to a prescription presented an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days. Under this proposal, the enrollee and his or her prescriber generally will decide if a medication supply of less than 30 days will be appropriate, and if so, the daily cost-sharing rate for the medication will be applied by the Part D sponsor based on the days supply dispensed.

Potential savings of a daily cost-sharing rate requirement on Part D sponsors will come from a reduction of the estimated $1.4 billion in costs noted above which will be offset by some additional dispensing fees. We previously estimated the potential savings to the Part D program to be $140 million in 2013 alone, and over $2.4 billion total by 2018 as described in section II.D.6. of this final rule with comment period. However, because we are revising the applicability date of this requirement to January 1, 2014, we have updated the cumulative savings in 2018 to roughly $1.8 billion, as also noted in section II.D.6. of this final rule with comment period.

Aside from the additional dispensing fees, we expect the other regulatory impact costs imposed by the proposed provisions to be the one-time costs for the industry to reprogram PBM systems to apply a daily cost-sharing rate. In this regard, we estimate that the number of hours for 28 PBMs and 12 plan organizations to reprogram their systems to establish and apply a daily copayment rate is 80 hours per processor or plan organization, for a total one-time burden of 3,200 hours (40 $\times$ 80). The estimated cost associated with such reprogramming is the estimated number of hours multiplied by the estimated hourly rate of $145.37 (Department of Labor, Bureau of Labor Statistics, Computer Software Engineers-Applications), which equals $465,184.

We did not receive any comments on this specific section, and are finalizing the requirement as discussed in section II.D.6. of this final rule with comment period.

18. Technical Corrections to Enrollment Provisions

We proposed technical changes that correct cross-references that should have been updated in previous rulemaking. These changes are technical corrections and do not represent a burden for small businesses, rural hospitals, States, or the private sector. We received no comments on the regulatory impact analysis of this proposal and, therefore, are finalizing this provision without modification.

19. MA and Part D Disclosure Requirements to Cost Contract Plans

We are proposing to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans. Our regulations at § 422.111 and § 423.128 require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. They also require the provision of certain information about request and establish requirements with respect to dissemination of explanations of benefits, customer service call centers, and Internet Web sites.

For each entity, we estimate that it will take 12 hours to develop and submit the required information. This includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, and 4 hours to print and disclose information to the beneficiaries. We estimate 20 cost contractors will be affected annually by this requirement, resulting in a total annual burden of 240 hours. We estimate, based on an hourly wage of $21.93 (hourly rate for a GS–10 step 1) plus 48 percent for fringe benefits and overhead, that this requirement will result in a total annual burden of $7,789 rounded. We did not receive public comments on the regulatory impact for this provision but are revising it to more accurately reflect the labor associated with the provision. In the October 2011 proposed rule, we based costs on the activities of a compliance officer instead of those of a GS–10 step 1.

20. Denials of SNP Applications and SNP Appeal Rights

We estimate that the proposed provision will have a minimal impact resulting from administrative costs incurred by the small number of SNP applicants that we expect will receive application denials and the small percentage of denied applicants that we expect will appeal our denial decision. For those organizations that do appeal the denial of their SNP application, a minimal number of professional staff working over a short period of time will be required to prepare and present the organization's appeal.

We estimate that the total annual hourly burden for developing and presenting a case for us to review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing SNP to research, draft, submit, and present their arguments to CMS. Based on SNP application denials from contract year 2012, out of the approximately 400 SNP applications received, 8 of these applications were denied and all 8 denials were appealed. In contract year 2011, 8 SNP applications were denied and none of these denials were appealed. Taking the average of the last 2 years, we estimate that approximately 4 denied applicants will appeal the denial of the SNP application. We further estimate that 1 attorney working for 8 hours could complete the documentation to be submitted for each application denial, The estimated annual cost to all of the MA organizations, the aggregate, that have been denied to offer a SNP associated with this provision (assuming an attorney billing $250 per hour) is $8,000 (32 hours × $250) or when rounded, to approximately $0.01 million per year.

21. Contract Requirements for First Tier and Downstream Entities in Subcontracts

The regulations at § 422.504(i) and § 423.505(i) require MA organizations and Part D sponsors to require all of the first tier, downstream, and related entities to which they have delegated the performance of certain Part C or D functions to agree to certain obligations. We believe that the most legally effective and direct way to ensure that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities is by requiring all contracts among those entities to specifically reference each party's obligations to the sponsor, as enumerated in § 422.504(i) and § 423.505(i). Thus, the regulation has been changed to address this need. Specifically, we deleted the term ''written arrangements'' throughout § 422.504(i) and § 423.505(i) and in each instance replace it with ''each and every contract.''

The proposed changes will not result in any additional costs since these types of contracts are already in use and required by regulation. Thus, the strengthening of the language to ensure that the sponsor is responsible for downstream entities is merely clarifying an existing requirement and eliminating potential loopholes.

22. Valid Prescriptions

In the § 423.100 proposed definition of ''valid prescription'' and the § 423.104 requirement of a ''valid prescription,'' we will codify our longstanding policy of deferring, when applicable, to State law to determine whether a prescription is valid such that the prescribed drug may be eligible for Part D coverage.

The changes made to this regulation will not result in any additional costs. Not only have we expected that prescriptions will be valid under applicable State law since the beginning of the Part D program, but also prescribers and pharmacies remain subject to applicable State laws regarding valid prescriptions. Furthermore, private contracts regarding Part D drugs (such as those between MA organizations or Part D sponsors and pharmacies) likely also require valid prescriptions. In light of the above realities, it is not unreasonable to presume that MA organizations, Part D sponsors, PBMs, and pharmacies are already taking steps to write prescriptions that are valid under applicable State law. Accordingly, we do not believe codifying the valid prescription requirement will change current practices.

23. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

Current regulations require that unless a beneficiary is in a LTC setting, the comprehensive medication review (CMR) must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. Section 10328 of the Affordable Care Act amended section 1860D–4(c)(2) of the Act to require that all targeted beneficiaries be offered a CMR. Accordingly, we proposed a change to § 423.153 to require that Part D sponsors offer a CMR to beneficiaries in LTC settings, but permitting the sponsor to allow the pharmacist or other qualified provider to perform the CMR without the beneficiary in cases when the beneficiary is in a LTC facility and is cognitively impaired and thus, cannot accept the sponsor's offer of a CMR. We anticipated that the impact of this proposed revision would clarify the CMR process for sponsors by allowing pharmacists and other qualified providers to ascertain whether the patient is willing and able to participate in a CMR before administering it. We incorrectly stated in the October 2011 proposed rule that we did not anticipate any costs or savings associated with this change. However, there will be a modest increase based on the requirement to offer CMRs to beneficiaries residing in LTC settings with written summaries and provide the summaries and action plans in a standardized format that complies with the requirements specified by CMS. We estimate that 215,000 beneficiaries in LTC settings are eligible for MTM services and 10 percent of those beneficiaries will receive an annual CMR. We also estimate that the average CMR requires 35 minutes to complete and the average hourly compensation (including fringe benefits, overhead, general and administrative expenses and fee) of the MTM provider is $120 (labor cost per CMR is $70), and that it costs $0.91 to print and mail a CMR summary in CMS' standardized format. Therefore, the estimated total annual cost of providing CMRs in LTC settings is $1,524,565 ($70.91/CMR × 21,500 CMRs). The estimate reflects costs previously calculated in the OCN 0938–1154.

24. Coordination of Part D Plans With Other Prescription Drug Coverage

The regulation will be explicit that sponsors, when providing Part D benefits to enrollees of EGWPs, are subject to the same requirements as sponsors providing Part D coverage in the individual market unless such requirements are explicitly waived. Since this change is being made to clarify an existing policy, we do not anticipate any effect on costs or savings on any specific entity.

25. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

The inconsistent use of identifiers by prescribers on Part D claims has hindered some of our efforts to combat fraud and abuse activities. Therefore, we proposed to require, effective January 1, 2013, that Part D sponsors include only active and valid individual prescriber NPIs as identifiers in PDEs submitted to CMS.

The impact associated with these proposed regulations is: (1) The annual cost for PBMs and plan organizations to contract with a commercial vendor or with network pharmacies to provide prescriber ID validation services; or (2) the annual cost required for PBMs and plan organizations to build their own databases of active and valid prescriber NPIs. We estimated a one-time burden for an estimated 28 PBMs and 12 plan organizations to negotiate and execute a contract with a commercial vendor to provide prescriber ID validation services to be negligible, particularly since PBMs and plan organizations typically have in-house counsel or law firms on retainer. The estimated annual cost of such a contract is $160,000, which is the mid-point of estimates we have seen for such a contract. Therefore, the estimated annual cost of such a contract for 40 PBMs and plan organizations is $6,400,000 (40 × 160,000). However, preliminary results of an analysis of coverage year 2011 PDEs submitted to date conducted by a contractor to CMS indicate that approximately 90 percent already contain valid individual NPIs. Therefore, this estimation should be reduced to reflect that a certain amount of cost associated with prescriber ID validation has already been absorbed by the industry. Therefore, we assume that 80 percent of the industry needs to acquire additional prescriber ID validation capacity in order to submit only PDEs that contain active and valid individual prescriber NPIs to CMS. Thus, the estimated annual cost to PBMs and plan organizations of a contract with a commercial vendor to perform prescriber NPI validation services is $5,120,000 (6,400,000 × 0.8).

With respect to PBMs and plan organizations that decide to build their own databases of active and valid prescriber NPIs (or to contract with network pharmacies for prescriber validation services), we assume that they will only do so if the cost is equal to or less than contracting with a commercial vendor for such services, and therefore, no estimation of the costs to do so is necessary.

Since approximately 90 percent of PDEs for coverage year 2011 submitted to CMS already contain valid individual NPIs, an estimated 95 percent of physicians have an NPI, and prescribers may voluntarily obtain an NPI to facilitate coverage of their patients' prescriptions, we estimate negligible costs associated with any PDE that cannot be submitted to CMS for lack of an NPI.

After consideration of the public comments received, we are modifying this requirement as discussed in section II.E.11. of this final rule with comment period (Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)). However, we are not modifying this regulatory impact analysis, since none of the comments received specifically addressed this analysis, and we believe our modifications do not necessitate a change to this analysis.

TABLE 8—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Fiscal year ($ in millions)						Total ($ in millions) FYs 2013–2018
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement	423.2315	3,760.00	4,260.00	4,810.00	5,440.00	6,050.00	6,730.00	31,050.00
Payment Processes for Part D Sponsors	423.2320	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Provision of Applicable Discounts	423.2325	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Compliance and Civil Money Penalties	423.2340	1.18	1.32	1.48	1.67	1.88	2.11	9.64
Other Manufacturer Costs	423.2315	13.03	13.03	13.03	13.03	13.03	13.03	78.18
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	423.100	200.00	280.00	300.00	330.00	360.00	390.00	1,860.00
Who May File Part D Appeals with the Independent Review Entity	423.600	1.05	1.05	1.05	1.05	1.05	1.05	6.30
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)	422.102	−30.71	−28.67	−21.71	−20.16	−17.99	−17.98	−137.22
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program	423.100 423.104 423.153	0.50	−150.00	−260.00	−360.00	−460.00	−580.00	−1,809.50
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights	422.500	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Apply MA and Part D disclosure requirements to cost contract plans	417.427	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Access to covered Part D drugs through the use of standardized technology and NPIs	423.120	5.12	5.12	5.12	5.12	5.12	5.12	30.72
MTM Comprehensive Medication Reviews in LTC Settings	423.153	1.52	1.52	1.52	1.52	1.52	1.52	9.12

TABLE 8—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018—Continued

Provision(s)	Regulation section(s)	Fiscal year ($ in millions)						Total ($ in millions) FYs 2013–2018
		2013	2014	2015	2016	2017	2018	
Total Impact ($ in millions)	....	3,977.03	4,408.71	4,875.83	5,437.57	5,979.95	6,570.19	31,249.28

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 9—ESTIMATED COSTS AND SAVINGS TO THE FEDERAL GOVERNMENT BY PROVISION FOR FYS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Fiscal year ($ in millions)						Total ($ in millions) (FYs 2013–2018)
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement	423.2315	160.00	190.00	210.00	260.00	260.00	260.00	1,340.00
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	423.100	200.00	280.00	300.00	330.00	360.00	390.00	1,860.00
Who May File Part D Appeals with the Independent Review Entity	423.600	0.97	0.97	0.97	0.97	0.97	0.97	5.84
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program	423.100 423.104 423.153	0.00	−150.00	−260.00	−360.00	−460.00	−580.00	−1,810.00
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)—Medicare	422.102	−29.80	−27.63	−20.76	−19.08	−17.16	−17.13	−131.56
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)—Federal Medicaid	422.102	−0.67	−0.64	−0.59	−0.55	−0.52	−0.53	−3.50
Total ($ in millions)	....	330.50	292.70	229.62	211.34	142.29	53.31	1,260.78

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 10—ESTIMATED COSTS TO MA ORGANIZATIONS AND PART D SPONSORS BY PROVISION FOR FYS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Costs per fiscal year ($ in millions)						Total (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Payment Processes for Part D Sponsors	423.2320	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Provision of Applicable Discounts	423.2325	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Who May File Part D Appeals with the Independent Review Entity	423.600	0.08	0.08	0.08	0.08	0.08	0.08	0.45
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program	423.100 423.104 423.153	0.5	0	0	0	0	0	0.5
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)—Medicare	422.102	0.06	0.06	0.06	0.06	0.06	0.06	0.36
Apply MA and Part D Disclosure Requirements to Cost Contract Plans	417.427	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights	22.500	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Access to covered Part D drugs through the use of standardized technology and NPIs	423.120	5.12	5.12	5.12	5.12	5.12	5.12	30.72
MTM Comprehensive Medication Reviews in LTC Settings	423.153	1.52	1.52	1.52	1.52	1.52	1.52	9.12
Total ($ in millions)	....	32.62	32.12	32.12	32.12	32.12	32.12	193.19

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 11—ESTIMATED COSTS TO MANUFACTURERS BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Costs per fiscal year ($ in millions)						Total (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement	423.2315	3,600.00	4,070.00	4,600.00	5,180.00	5,790.00	6,470.00	29,710.00
Other Manufacturer Costs	423.2315	13.03	13.03	13.03	13.03	13.03	13.03	78.18
Compliance and Civil Money Penalties	423.2340	1.18	1.32	1.48	1.67	1.88	2.11	9.64

TABLE 11—ESTIMATED COSTS TO MANUFACTURERS BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018—Continued

Provision(s)	Regulation section(s)	Costs per fiscal year ($ in millions)						Total (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Total ($ in millions)		3,614.21	4,084.35	4,614.51	5,194.70	5,804.91	6,485.14	29,797.82

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 12—ESTIMATED SAVINGS TO STATES BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Savings per fiscal year ($ in millions)						Total savings (FYs 2013–2018) ($ in millions)
		2013	2014	2015	2016	2017	2018	
Benefit Flexibility for Certain Dual Eligible Special Needs Plans	422.102	−0.50	−0.48	−0.44	−0.41	−0.39	−0.40	−2.62

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

D. Expected Benefits

1. Medicare Coverage Gap Discount Program Agreement

The rule codifies a number of requirements that must be included in the manufacturer Discount Program Agreement that generally must be signed by a manufacturer to allow Part D coverage of the manufacturers applicable drugs. These requirements are fundamental to ensuring that participating manufacturers pay all applicable discounts for applicable drugs received by applicable beneficiaries while in the coverage gap. We believe that a well-implemented Discount Program will increase beneficiary adherence to medication regimens that can improve their health by lowering their pharmaceutical costs at the point-of-sale.

2. Payment Processes for Part D Sponsors

The rule requires CMS to facilitate distribution of the applicable discount to beneficiaries by requiring that CMS provide an interim discount payment to Part D sponsors. That interim discount payment will be subsequently reconciled against manufacturer payments for discounts provided to beneficiaries. This provision will help Part D sponsors maintain operations with minimal, if any, effect on cash flow. This will help ensure that Part D sponsors provide the applicable discount to applicable beneficiaries at point-of-sale.

3. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries

The rule requires Part D sponsors to calculate the applicable discount that should be provided to applicable beneficiaries in the coverage gap. Applicable beneficiaries will, therefore, have minimal need to determine when they qualify for the gap discount and when they are no longer in the gap. In addition, Part D sponsors will likely automate discount calculations, potentially reducing errors and the need for beneficiaries to file an appeal that challenges the discount amount.

4. Manufacturer Discount Payment Audits and Dispute Resolution

We believe that the audit and dispute programs will both contribute to the stable operation of the Discount Program. Both programs are intended to provide an equitable means to resolve manufacturer concerns, enhance program integrity and, therefore, program stability. A predictable and stable Discount Program will help beneficiaries plan their finances and health care costs over time.

5. Beneficiary Dispute Resolution

The traditional Medicare program provides a means for beneficiaries to challenge Medicare decisions to ensure they receive needed benefits. We believe that beneficiaries will gain the same benefit from a dispute resolution program associated with the Discount Program. Further, extending the existing Part D beneficiary dispute resolution process to the Discount Program will reduce the need for beneficiaries to learn a new set of dispute procedures.

6. Compliance Monitoring and Civil Money Penalties

Our expectation is that manufacturers will generally comply with the terms of the Discount Program Agreement and the Discount Program. We understand that manufacturers may still err and that such errors can disrupt program operations. Our intention is to use compliance actions, including penalties, to encourage reduced manufacturer errors and maintain a predictable program for beneficiaries.

7. Termination of Agreement

We believe that CMS' ability to terminate the Agreement upon extreme non-compliance by manufacturers will likely encourage manufacturers to address issues quickly. We believe that prompt resolution of significant concerns will create minimal disruption to the program and inconvenience of beneficiaries.

8. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs

Part D coverage of benzodiazepines and barbiturates potentially improves beneficiary access to these drugs and reduces beneficiary out-of-pocket costs for non-Part D covered drugs. In addition, State costs are reduced in those States that have been paying for these drugs.

9. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

This final rule with comment period requirement to change the actuarial value calculation for creditable coverage to exclude the additional value of gap coverage consistent with the determination of the RDS actuarial value of prescription drug coverage will enable beneficiaries who switch from an RDS plan or other creditable prescription drug coverage to a Part D plan to do so without incurring a late enrollment penalty.

10. Who May File Part D Appeals With the Independent Review Entity

The changes to § 423.600 and § 423.602 will allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees. These changes will reduce the burden on enrollees and their prescribers because they will no longer have to submit a properly executed AOR form in cases where the prescriber wishes to request a reconsideration on behalf of a Part D plan enrollee. Additionally, physicians and prescribers are in the best position to anticipate and provide the appropriate medical documentation needed to support coverage for Part D enrollees' medications. We believe that by allowing a physician or other prescriber to request a reconsideration on an enrollee's behalf, it will further improve the enrollee's access to the Part D appeals process and assist enrollees in obtaining coverage of medically necessary medications.

11. Termination for Lower-Than-Three-Star-Performance Ratings

The benefit of this change is that we will leverage the annual performance ratings to remove from the MA and Part D programs poor performing organizations, thereby strengthening the programs and protecting Medicare beneficiaries.

12. Exclusion for Sponsors of Contracts Terminated for Cause

The benefit of this change is that we will ensure that organizations that demonstrated extremely poor performance have their performance history reviewed as part of the application process for an appropriate amount of time, thereby strengthening the programs and protecting Medicare beneficiaries.

13. Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)

We believe that allowing certain dual eligible SNPs that meet high integration and performance based standards to offer supplemental benefits beginning contract year 2013 will advance our overall goal of better integrating care for dual eligible beneficiaries, keeping beneficiaries at risk of institutionalization in their homes, lowering dual eligible beneficiaries' utilization of health services, and lowering costs for the Medicaid and Medicare programs.

14. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

Requiring Part D sponsors to establish and apply a daily cost-sharing rate as previously described facilitates the ability of Medicare Part D enrollees to obtain trial fills of chronic medications, particularly those with higher cost-sharing and that are known to frequently be poorly tolerated. As noted previously, we believe trial fills will result in the avoidance of unused drugs, reduce drug costs, diminish the environmental issues caused by disposal of unused medications, and reduce opportunities for criminal and substance abuse caused by diversion of unused medications, all of which are growing concerns in the United States. While there may be additional waste generated by multiple fills when medications are continued after a trial fill or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), we believe the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables.

With respect to synchronization of medication refills specifically, we also note that at least one study supports the notion that synchronization may assist enrollees in adhering to prescription treatment regimens that involve multiple prescriptions. In addition, we believe the ability to synchronize medications will be convenient for those enrollees who take advantage of the opportunity and their prescribers, by enabling fewer trips to the pharmacy and fewer prescription requests of prescribers by enrollees through the ability to consolidate pharmacy trips and prescriber office visits and phone calls.

We received no specific comments on this section.

15. Apply MA and Part D Disclosure Requirements to Cost Contract Plans

We believe that our requirement that cost contract plans disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities, and an explanation of benefits will ensure that the beneficiaries have information to help them make best choices for their health care needs.

16. Denial of SNP Applications and SNPs Appeal Rights

Our intent in proposing this provision is to give us the explicit authority to deny SNP applications that demonstrate that the applicant does not meet the requirements to operate a SNP, which have been incorporated into the MA application. This proposed change will ensure that the only MA organizations that are able to offer a SNP are those that meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs, thereby strengthening the program and protecting Medicare beneficiaries. Additionally, to ensure a fair and comprehensive review of these SNP applications, we propose to allow applicants who have been determined unqualified to offer a SNP the right to an administrative review process.

17. Clarification of Contract Requirements for First Tier and Downstream Entities

This clarification ensures that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities, thereby strengthening the programs and protecting Medicare beneficiaries.

18. Valid Prescriptions

By removing any doubt as to the appropriate source of law to consult when determining whether a prescription is valid, this regulation will benefit federal law enforcement agencies. We do not believe, however, that there is a quantifiable monetary value to easing prosecutions in this manner.

19. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

The expected benefits of the revisions to § 423.153 are that Part D sponsors will be required to offer all targeted beneficiaries in LTC facilities the opportunity to participate in a CMR, but in the event the beneficiary is cognitively impaired and unable either to respond to the offer or to participate in a CMR, the pharmacist or qualified provider may proceed with a CMR that is informative for the beneficiary's prescriber and/or caregiver without interacting with the beneficiary.

20. Coordination of Part D Plans With Other Prescription Drug Coverage

We are clarifying the regulation at § 423.458 regarding the application of waivers to EGWPs. We expect that this clarification will benefit Medicare beneficiaries enrolled in such plans by ensuring them the same protections as those afforded Medicare beneficiaries enrolled in individual market Part D plans where such protections have not been explicitly waived.

21. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

In addition to supporting our fraud and abuse activities, accurate data on prescriptions through the consistent use of valid NPIs on PDEs allows us to serve beneficiaries when using data in various initiatives whose purpose is to foster higher quality and more efficient coordination of care for individuals and groups of individuals.

We received no specific comments on this section, and therefore are not modifying our policy based on such comments. However, we are modifying our proposal, as described in section II.E.11. of the final rule with comment period, Access to Covered Part D Drugs through Use of Standardized Technology and National Provider Identifiers (§ 423.120), based on general comments we received.

E. Alternatives Considered

1. Affordable Care Act AND MIPPA Provisions

We did not consider alternatives for the following provisions, as their implementation was mandated by the Affordable Care Act and MIPPA:

• Inclusion of Benzodiazepines and Barbiturates

• Pharmacy Benefit Manager's Transparency Requirements

2. Coverage Gap Discount Program

The Affordable Care Act mandated implementation of the Coverage Gap Discount Program and further specified that the associated manufacturer discounts had to be made available at point-of-sale. An alternative model for point-of-sale administration of the discount will involve a third party administrator directly adjudicating the discount payment to pharmacies. In this model, the pharmacy will submit the Part D claim to the Part D sponsor and receive information on the response that will direct the pharmacy to bill the third party for applicable claims. However, while this model initially showed promise, neither the current HIPAA electronic pharmacy claims billing standard nor the next HIPAA approved version of the billing standard could support the transfer of information from the Part D sponsor that will be necessary to specify the appropriate claims and appropriate discount amounts to be billed to the third party administrator, or allow for accurate coordination of benefits among payers.

3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

We clarified our regulations at § 423.56 to define creditable prescription drug coverage consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d). This is a clarification to an existing calculation that is already being used by organizations providing creditable coverage, therefore, there is no cost impact on these organizations.

4. Who May File Part D Appeals With the Independent Review Entity

As previously mentioned, the changes to § 423.600 and § 423.602 will allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees. We considered maintaining the status quo, which would require physicians and other prescribers to obtain an AOR form in order to request a reconsideration by the IRE on behalf of their patients. However, given our program experience since the inception of the Part D program, we realize that this approach results in an undue burden on both enrollees and their prescribing physicians or prescribers and can create an unintended barrier to enrollees accessing the appeals process. Consequently, we are finalizing the change previously highlighted in this rule.

5. Termination or Non-Renewal of a Medicare Contract Based on Poor Plan Performance Ratings

We did not consider alternatives for this regulation since it is necessary to ensure compliance.

6. Exclusion for Sponsors of Contracts Terminated for Cause

We considered keeping the look-back period at 14 months, but we determined it will be insufficient to accomplish our needs and thus a longer look-back period was necessary. We also considered longer look-back periods, but we deemed them to be to excessive.

7. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)

In our proposed rule, we considered affording this benefit flexibility only to those plans that met the definition of a fully integrated dual eligible special needs plan (FIDE SNP) as defined at 42 CFR 422.2. We also proposed limiting this benefit flexibility to only those FIDE SNPs that enrolled dual eligible beneficiaries that received full Medicaid benefits. In this final rule with comment period, we are not limiting this benefit flexibility to FIDE SNPs, but are instead allowing D–SNPs that meet integration and performance-based standards established by CMS to qualify for this benefit flexibility. We believe that expanding this flexibility to a larger pool of D–SNPs that are integrating care for dual eligible beneficiaries is still consistent with our overall objective of preventing institutionalization, and will give more dual eligible beneficiaries across the country access to these additional supplemental benefits.

8. Establishment and Application of Daily Cost-Sharing Rates as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

We considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and must be dispensed in a 15-day initial script to ensure cost effectiveness without ''wasting'' or ''discarding'' of used medications. We have learned through representatives of the program that MaineCare has achieved overall savings for the two consecutive state fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there was very good acceptance of the program and very little confusion upon implementation. While we acknowledge the savings benefits of the MaineCare approach, we believe that leaving the decision to obtain less than a month's supply of a prescription with the enrollee and his or her prescriber and pharmacist may be better suited for the Medicare Part D program, but we sought specific comment on this belief.

Comment: A few commenters offered a ''copayment by days supply'' alternative.

Response: For these reasons discussed in section II.D.6. of this final rule with comment period (Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program), we decline to adopt this alterative.

9. Clarification of Contract Requirements for First Tier and Downstream Entities

We did not consider alternatives for this regulation since it is necessary to ensure compliance and is the most effective ''no-cost'' means to achieving it.

10. Valid Prescriptions

We did not consider alternatives for this regulation as it reflects existing state laws.

11. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

Section 10328 of the Affordable Care Act requires that a CMR be offered to all targeted beneficiaries, regardless of setting. Thus, the only alternative to this revision would be to have the pharmacist or provider attempt to perform a CMR with a LTC resident who is not capable of participating. However, by requiring a CMR to be offered to all targeted beneficiaries residing in LTC our revisions to the regulations will give these beneficiaries, who typically have chronic conditions that are managed by medication, the opportunity to participate in the CMR and comprehend the medication action plan as a result of the CMR. In cases when the beneficiary is unable to accept the offer of a CMR, the beneficiary will still benefit from having a CMR performed by a pharmacist or other qualified provider with the beneficiary's prescriber and/or caregiver without interacting with the beneficiary.

12. Coordination of Part D Plans With Other Prescription Drug Coverage

We considered the alternative, which was to remain silent in regulation. However, we believe that in order to facilitate beneficiary protections it is better to be clear that, unless waived, the same Medicare rules apply to sponsors of EWGPs as they do to sponsors of individual market plans. This ensures Medicare beneficiaries enrolled in EGWPs receive the same patient protections as beneficiaries enrolled in individual market plans.

13. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

We considered requiring prescribers to enroll in Medicare in order for their prescriptions to be covered by the Part D program, but were concerned about the potential impact of such a requirement on enrollee access to needed medications. We also considered permitting any 1 of 4 types of prescriber identifiers to be submitted on PDEs, but we believe this option is not in line with Congressional intent regarding the use of NPIs as provider identifiers.

Comment: A commenter supported our policy to not require physicians to enroll in Medicare in order for their prescriptions to be covered by the Part D program.

Response: We appreciate the commenter's support.

After consideration of the other public comments received, we are modifying this requirement as discussed in section II.E.11. of this final rule with comment period, (Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)).

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 13, we have prepared an accounting statement showing the classification of the expenditures, costs, and savings associated with the provisions of the proposed rule for FY 2013 through 2018.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS, FROM FY 2013 TO FY 2018

[$ In millions]

Category	Transfers		
	Units discount rate		Period covered
	7%	3%	
Annualized Monetized Transfers	$220.3	$214.5	FYs 2013–2018
From Whom To Whom?	Federal Government to MA Organizations and Part D Sponsors		
Annualized Monetized Transfers	−$0.44	−$0.44	FYs 2013–2018
From Whom To Whom?	States to Medicaid Providers		
	Costs (All other provisions)		
	Units discount rate		Period covered
	7%	3%	
Annualized Costs to MA organizations and Part D Sponsors	$32.2	$32.2	FYs 2013–2018
Annualized Costs to Manufacturers	$4,853.7	$4,916.9	FYs 2013–2018

(* Monetized figures in 2011 dollars.)

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule with comment period.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 2. Section § 417.422 is amended by revising paragraph (d) to read as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *

(d) During an enrollment period of the HMO or CMP, completes the HMO's or CMP's application form or another CMS-approved election mechanism and gives whatever information is required for enrollment;

* * * * *

■ 3. Subpart K is amended by adding § 417.427 to read as follows:

§ 417.427 Extending MA and Part D program disclosure requirements to section 1876 cost contract plans.

(a) The procedures and requirements relating to disclosure in § 422.111 and § 423.128 apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying the provisions of §§ 422.111 and 423.128, references to part 422 and part 423 of this chapter must be read as references to this part, and references to MA organizations and Part D sponsors as references to HMOs and CMPs.

■ 4. Section 417.432 is amended by revising paragraph (d) to read as follows:

§ 417.432 Conversion of enrollment.

* * * * *

(d) *Application form.* The individual who is converting must complete an application form or another CMS-approved election mechanism as described in § 417.430(a).

* * * * *

■ 5. Section 417.460 is amended by adding paragraphs (c)(3) and (4) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(4) *Exception for reinstatement.* A beneficiary's enrollment in the plan will not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

§ 417.492 [Amended]

■ 6. Section 417.492 is amended as follows:

■ A. In paragraph (a)(1)(i), '';'' is removed and ''; and'' is added in its place.

■ B. In paragraph (a)(1)(ii), ''; and'' is removed and ''.'' is added in its place.

■ C. By removing paragraph (a)(1)(iii).

■ D. By removing paragraph (b)(1)(iii).

■ 7. Section 417.801 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 417.801 Agreements between CMS and health care prepayment plans.

* * * * *

(d) * * *

(1) * * *

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law. This includes, but is not limited to, the following:

(A) Failure to provide for and document adequate access to providers.

(B) Failure to comply with CMS requirements concerning provision of data and maintenance of records.

(C) Failure to comply with financial requirements specified at § 417.806; or

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 8. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 422.60 [Amended]

■ 9. In § 422.60, paragraph (c)(1) is amended by removing the reference ''§ 422.80'' and adding in its place the reference ''§ 422.2262''.

■ 10. Section 422.100 is amended by adding paragraph (l) to read as follows:

§ 422.100 General requirements.

* * * * *

(l) Coverage of DME. MA organizations—

(1) Must cover and ensure enrollees have access to all categories of DME covered under Part B; and

(2) May, within specific categories of DME, limit coverage to certain DME brands, items, and supplies of preferred manufacturers provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all DME brands, items, and supplies of preferred manufacturers.

(ii) Its enrollees have access to all medically-necessary DME brands, items, and supplies of non-preferred manufacturers.

(iii) At the enrollees' request, it provides for an appropriate transition process for new enrollees during the first 90 days of their coverage under its MA plan, during which time the MA organization will do the following:

(A) Ensure the provision of a transition supply of DME brands, items, and supplies of non-preferred manufacturers.

(B) Provide for the repair of DME brands, items, and supplies of non-preferred manufacturers.

(iv) It makes no negative changes to its DME brands, items, and supplies of preferred manufacturers during the plan year.

(v) It treats denials of DME brands, items, and supplies of non-preferred manufacturers as organization determinations subject to § 422.566.

(vi) It discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a DME brand, item, or supply of a non-preferred manufacturer as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

(vii) It provides full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories annually determined by CMS to require full coverage.

■ 11. Section 422.101 is amended by revising paragraph (d)(1) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(1) *Single deductible.* MA regional and local PPO plans, to the extent they apply a deductible as follows:

(i) Must have a single deductible related to all in-network and out-of-network Medicare Part A and Part B services.

(ii) May specify separate deductible amounts for specific in-network Medicare Part A and Part B services, to the extent these deductible amounts apply to the single deductible amount specified in paragraph (d)(1)(i) of this section.

(iii) May waive other plan-covered items and services from the single deductible described in paragraph (d)(1)(i) of this section.

(iv) Must waive all Medicare-covered preventive services (as defined in § 410.152(l)) from the single deductible described paragraph (d)(1)(i) of this section.

* * * * *

■ 12. Section 422.102 is amended by adding paragraph (e) to read as follows.

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, dual eligible special needs plans that meet a high standard of integration and minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

(1) Operated in the MA contract year prior to the MA contract year for which it is submitting its bid; and

(2) Offers its enrollees such benefits without cost-sharing or additional premium charges.

■ 13. Section 422.111 is amended by adding paragraph (i) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(i) *Provision of information required for access to covered services.* MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. The cards must comply with standards established by CMS.

■ 14. Section 422.216 is amended by revising paragraph (d)(1) to read as follows:

§ 422.216 Special rules for MA private fee-for-service plans.

* * * * *

(d) * * *

(1) *General information.* An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of § 422.111(b)(12).

* * * * *

■ 15. Section 422.500 is amended by revising paragraph (a) to read as follows:

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan, including MA organizations offering a specialized MA plan for special needs individuals. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

* * * * *

■ 16. Section 422.501 is amended as follows:

■ A. By revising paragraph (a).

■ B. In paragraph (c)(1)(i) by removing ''; or'' and adding in its place ''.''.

■ C. By adding paragraph (c)(1)(iii).

■ D. By revising paragraph (e).

The addition and revisions read as follows:

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

* * * * *

(c) * * *

(1) * * *

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

* * * * *

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may not be resubmitted until the beginning of the application cycle for the following contract year.

* * * * *

■ 17. Section 422.502 is amended as follows:

■ A. In paragraph (a)(1), by removing the phrase ''MA contract solely'' and adding in its place the phrase ''MA contract or for a Specialized MA Plan for Special Needs Individuals solely''.

■ B. In paragraph (b)(1), by removing the phrase ''If an MA organization'' and adding in its place ''Except as provided in paragraphs (b)(2) through (b)(4) of this section, if an MA organization''.

■ C. By adding paragraphs (b)(3) and (4).

■ D. In paragraph (c) introductory text, by removing the phrase ''MA contract under this part'' and adding in its place the phrase ''MA contract or to be designated a Specialized MA Plan for Special Needs Individuals under this part''.

■ E. By revising paragraphs (c)(2) and (c)(3)(i).

The additions and revision read as follows:

§ 422.502 Evaluation and determination procedures.

(b) * * *

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) * * *

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) * * *

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

* * * * *

■ 17. Section 422.504 is amended as follows:

■ A. By adding paragraphs (a)(17) and (18).

■ B. By revising paragraphs (i)(3)(iii), (i)(4)(i), (ii), (iii), (iv) introductory text and (i)(5).

The additions and revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(17) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(18) To maintain a Part C summary plan rating score of at least 3 stars. A Part C summary plan rating is calculated by taking an average of a contract's Part C performance measure scores.

* * * * *

(i) * * *

(3) * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the MA organization's contractual obligations.

(4) * * *

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract must specify that either—

* * * * *

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's contract with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

* * * * *

■ 18. Section 422.510 is amended by adding paragraph (a)(14) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(14) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

* * * * *

■ 19. Section 422.641 is amended by adding paragraph (d) to read as follows:

§ 422.641 Contract determinations.

* * * * *

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in §§ 422.2 and 422.4(a)(1)(iv).

■ 20. Section § 422.660 is amended by adding paragraphs (a)(5) and (b)(5) to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) * * *

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) * * *

(5) During a hearing to review a determination as described at § 422.641(d) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

* * * * *

■ 21. Section 422.2274 is amended as follows:

■ A. By revising paragraph (a)(1)(i).

■ B. By removing and reserving paragraph (a)(1)(ii).

■ C. By revising paragraph (a)(1)(iii).

■ D. By adding paragraph (f).

The revisions and addition read as follows:

§ 422.2274 Broker and agent requirements.

* * * * *

(a) * * *

(1) * * *

(i) The compensation amount paid by plan sponsors to an independent broker or agent:

(A) For an initial enrollment of a Medicare beneficiary into an MA plan, must be at or below the fair market value (FMV) cut-off amounts published annually by CMS.

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

(ii) [Reserved].

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation amount (creating a 6-year compensation cycle).

* * * * *

(f) A plan sponsor must report annually, as directed by CMS—

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year; and

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 22. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–43, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–153, and 1395hh).

■ 23. Section 423.56 is amended by revising paragraphs (a) and (f)(3) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition. Creditable prescription drug coverage* means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

* * * * *

(f) * * *

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

* * * * *

■ 24. Section 423.100 is amended as follows:

■ A. By adding in alphabetical order the definition of ''Daily cost-sharing rate.''

■ B. By revising paragraph (2)(iii) of the definition of ''Incurred costs.''

■ C. In paragraph (2)(ii) of the definition of ''Part D drug,'' by removing the phrase ''smoking cessation agents'' and adding in its place the phrase ''smoking cessation agents; barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines''.

■ D. By revising the definition of ''Supplemental benefits.''

■ E. By adding in alphabetical order the definition of ''Valid prescription.''

The additions and revision read as follows:

§ 423.100 Definitions.

* * * * *

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case; or

(2) Coinsurance percentage under the enrollee's Part D.

* * * * *

Incurred costs * * *

(2) * * *

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

* * * * *

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

* * * * *

Valid prescription means a prescription that complies with all applicable State law requirements constituting a valid prescription.

■ 25. Section 423.104 is amended by adding paragraphs (h) and (i) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(h) *Valid prescription.* A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.

(i) *Daily cost-sharing rate.* Beginning January 1, 2014, a Part D sponsor is required to provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4).

■ 26. Section 423.120 is amended by adding paragraph (c)(5) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(5)(i) A Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

(ii) A Part D sponsor must ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug, by taking the steps described in paragraph (c)(5)(iii) of this section.

(iii) The sponsor must communicate at point-of-sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(iii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(*1*) Confirm that the NPI is active and valid; or

(*2*) Correct the NPI.

(B) If the pharmacy—

(*1*) Confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable; or

(*2*) Cannot or does not correct or confirm that the NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

(iv) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraphs (c)(5)(ii) and (iii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(v) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

* * * * *

■ 27. Section 423.153 is amended as follows:

■ A. In the introductory text for paragraph (b) by removing the phrase ''that -'' and adding in its place the phrase ''that address all of the following:''.

■ B. In paragraph (b)(1) by removing '';'' and adding in its place ''.''.

■ C. In paragraph (b)(2) by removing ''; and'' and adding in its place ''.''.

■ D. By adding paragraph (b)(4).

■ E. By revising paragraph (d)(1)(vii)(B).

The addition and revision read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(b) * * *

(4)(i) Establishes a daily cost-sharing rate and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, and in the case of a monthly copayment, multiplies the daily cost-sharing rate by the days supply actually dispensed—

(A) If the drug is in the form of a solid oral dose, subject to paragraph (b)(4)(i)(B) of this section and may be dispensed for a supply less than 30 days under applicable law;

(B) The requirements of this paragraph (b)(4)(i) do not apply to either of the following:

(*1*) Solid oral doses of antibiotics.

(*2*) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(ii) [Reserved]

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(B) *Annual comprehensive medication review with written summaries.* (*1*) The beneficiary's comprehensive medication review—

(*i*) Must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider; and

(*ii*) May result in a recommended medication action plan.

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

* * * * *

■ 28. Section 423.458 is amended by adding paragraph (c)(4) to read as follows:

§ 423.458 Application of Part D rules to certain Part D plans on or after January 1, 2006.

* * * * *

(c) * * *

(4) Employer-sponsored group prescription drug plans must comply with all applicable requirements under this part that are not specifically waived or modified in accordance with in paragraph (c)(3) of this section.

* * * * *

■ 29. Section 423.501 is amended by adding the definition of ''Bona fide service fees'' in alphabetical order to read as follows:

§ 423.501 Definitions.

* * * * *

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

* * * * *

■ 30. Section 423.503 is amended as follows:

■ A. In paragraph (b)(1), by removing the phrase ''If a Part D'' and adding in its place ''Except as provided in paragraphs (b)(2), (3), and (4) of this section, if a Part D''.

■ B. Adding paragraphs (b)(3) and (4).

The additions read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(3) If CMS has terminated, under § 423.509, or non-renewed, under § 423.507(b), a Part D plan sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part D program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

■ 31. Section 423.505 is amended as follows:

■ A. By adding paragraphs (b)(24) through (26).

■ B. By revising paragraphs (i)(3) introductory text, (i)(3)(iii), (i)(3)(v), and (i)(4)(i) through (iv).

The addition and revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(24) Provide applicable beneficiaries with applicable discounts on applicable drugs in accordance with the requirements in subpart W of Part 423.

(25) Maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality assurance activities related to the delivery of Part D services.

(26) Maintain a Part D summary plan rating score of at least 3 stars. A Part D summary plan rating is calculated by taking an average of a contract's Part D performance measure scores.

* * * * *

(i) * * *

(3) Each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following:

* * * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations.

* * * * *

(v) Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

(4) * * *

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Each and every contract must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) Each and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

■ 32. Section 423.509 is amended by adding paragraph (a)(13) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *

(a) * * *

(13) Achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1,

2012 are not included in the calculation of the 3-year period.

* * * * *

■ 33. Section 423.514 is amended as follows:

■ A. By redesignating paragraphs (d) through (g) as paragraphs (g) through (j), respectively.

■ B. By adding new paragraphs (d), (e), and (f).

The additions read as follows:

§ 423.514 Validation of Part D reporting requirements.

* * * * *

(d) *Reporting requirements for pharmacy benefits manager data.* Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following:

(1) The total number of prescriptions that were dispensed.

(2) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.

(3) The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.

(4) The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in § 423.501) that the PBM negotiates that are attributable to patient utilization under the plan.

(5) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(6) The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

(e) *Confidentiality of pharmacy benefits manager data.* Information disclosed by a Part D sponsor or PBM as specified in paragraph (d) of this section is confidential and must not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(f) *Penalties for failure to provide pharmacy benefits manager data.* The provisions of section 1927(b)(3)(C) of the Act are applicable to a Part D sponsor or PBM that fails to provide the required information on a timely basis or knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under section 1927 of the Act.

* * * * *

■ 34. Section 423.600 is amended by revising paragraphs (a) through (c) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

(c) In order for an enrollee or a prescribing physician or other prescriber (acting on behalf of an enrollee) to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

* * * * *

■ 35. Section 423.602 is amended by revising paragraph (a) to read as follows:

§ 423.602 Notice of reconsideration determination by the independent review entity.

(*a*) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS. When the prescribing physician or other prescriber requests the reconsideration on behalf of the enrollee, the IRE is also responsible for notifying the prescribing physician or other prescriber of its decision.

* * * * *

■ 36. Section 423.1000 is amended by adding paragraph (a)(3) to read as follows:

§ 423.1000 Basis and scope.

* * * * *

(a) * * *

(3) Section 1860D–14A(e)(2) of the Act specifies that the Secretary must impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with its Discount Program Agreement. Section 1860D–14A(e)(2)(B) of the Act makes certain provisions of section 1128A of the Act applicable to such civil money penalties imposed on manufacturers.

* * * * *

■ 37. Section 423.1002 is amended by revising the definition of ''Affected party'' to read as follows:

§ 423.1002 Definitions.

* * * * *

Affected party means any Part D sponsor or manufacturer (as defined in § 423.2305) impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

* * * * *

■ 38. Section § 423.2274 is amended as follows:

■ A. By revising paragraph (a)(1)(i).

■ B. By removing and reserving paragraph (a)(1)(ii).

■ C. By revising paragraph (a)(1)(iii).

■ D. By adding paragraph (f).

The revisions and addition read as follows:

§ 423.2274 Broker and agent requirements.

* * * * *

(a) * * *

(1) * * *

(i) The compensation amount paid by plan sponsors to an independent broker or agent—

(A) For an initial enrollment of a Medicare beneficiary into a PDP must be at or below the fair market value (FMV) cut-off amounts published annually by CMS; or

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

* * * * *

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation paid (creating a 6-year compensation cycle).

* * * * *

(f) Plan sponsor must report annually, as directed by CMS the following:

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year.

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

■ 39. Subpart W is added to read as follows:

Subpart W—Medicare Coverage Gap Discount Program

Sec.

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements regarding the following:

(a) Condition for coverage of applicable drugs under Part D.

(b) The Medicare Coverage Gap Discount Program Agreement.

(c) Coverage gap discount payment processes for Part D sponsors.

(d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(e) Manufacturer audit and dispute resolution processes.

(f) Resolution of beneficiary disputes involving coverage gap discounts.

(g) Compliance monitoring and civil money penalties.

(h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug.

In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in § 423.124, less any dispensing fee or vaccine administration fee.

Other health or prescription drug coverage means any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, including, in the case of employer group health or waiver plans, other than basic prescription drug coverage as defined in § 423.100.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by the CMS to carry out section 1860D–14A of the Act.

§ 423.2310 Condition for coverage of drugs under Part D.

(a) *Covered Part D drug coverage requirement.* Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:

(1) Participate in the Discount Program.

(2) Have entered into and have in effect an agreement described in § 423.2315(b).

(3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.

(b) *Exception to covered drug coverage requirement.* Paragraph (a) of this section does not apply to an applicable drug if CMS has made a determination that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

(a) *General rule.* The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D–14A (a)(1) of the Act.

(b) *Agreement requirements.* The manufacturer agrees to the following:

(1) All the applicable requirements and conditions set forth in this part and general instructions.

(2) Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors.

(3) Pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in § 423.2330(c)(3).

(4) Provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

(5) Collect, have available, and maintain appropriate data, including data related to manufacturer's labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program, for a period of not less than 10 years from the date of payment of the invoice.

(6) Comply with the audit and dispute resolution requirements in § 423.2330.

(7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including providing timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

(8) Maintain up-to-date NDC listings with the electronic database vendors for which the manufacturer provides NDCs for pharmacy claims processing.

(9) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract with CMS under section 1860D–14(A)(d)(3) of the Act.

(10) Pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in paragraph (b)(3) of this section and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS.

(11) Use information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program.

(c) *Timing and length of agreement.* (1) For 2011, a manufacturer must enter into a Discount Program Agreement not later than 30 days after the date of establishment of the model Discount Program Agreement.

(2) For 2012 and subsequent years, for a Discount Program Agreement to be effective for a year, a manufacturer must enter into a Discount Program Agreement not later than January 30th of the preceding year.

(3) Unless terminated in accordance with § 423.2345, the initial period of a Discount Program Agreement is 24 months and the agreement is automatically renewed for a 1-year period on January first each year for a period of 1 year thereafter.

(d) *Compliance with requirements for administration of the Program.* Each manufacturer with an agreement in effect under this subpart must comply with the requirements imposed by CMS or the third party administrator (as defined in § 423.2305) for purposes of administering the program.

§ 423.2320 Payment processes for Part D sponsors.

(a) *Interim payments.* CMS provides monthly interim coverage gap discount program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries.

(b) *Coverage Gap Discount Reconciliation.* CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program.

§ 423.2325 Provision of applicable discounts.

(a) *General rule.* On behalf of the manufacturers, Part D sponsors must provide applicable beneficiaries with applicable discounts on applicable drugs at the point-of-sale.

(b) *Discount determination.* (1) Part D sponsors must determine the following:

(i) Whether an enrollee is an applicable beneficiary (as defined in § 423.100).

(ii) Whether a Part D drug is an applicable drug (as defined in § 423.100).

(iii) The amount of the applicable discount (as defined in § 423.2305) to be provided at the point-of-sale.

(2) Part D sponsors must make retroactive adjustments to the applicable discount as necessary to reflect changes to the claim or beneficiary eligibility determined after the date of dispensing.

(3) Part D sponsors must determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and notify such beneficiaries.

(c) *Exception to point-of-sale requirement.* Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan.

(d) *Collection of data.* Part D sponsors must provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

(e) *Supplemental benefits.* (1) An applicable discount must be applied to beneficiary cost-sharing after supplemental benefits (as defined in § 423.100) have been applied to the claim for an applicable drug.

(2) No applicable discount is available if supplemental benefits (as defined in § 423.100) eliminate the coverage gap so that a beneficiary has zero cost-sharing.

(f) *Other health or prescription drug coverage.* An applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied.

(g) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

§ 423.2330 Manufacturer discount payment audit and dispute resolution.

(a) *Third-party Administration (TPA) audits.* (1) Manufacturers participating in the Discount Program may conduct periodic audits, no more often than annually, directly or through third parties as specified in this section.

(2) The manufacturer must provide the TPA with 60 days notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The manufacturer must have the right to audit a statistically significant sample of data and information held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s). Such data and information will be made available on-site, and with the exception of work papers, such information cannot be removed from the audit site.

(4) The auditor for the manufacturer may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *Manufacturer audits.* (1) A manufacturer is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS provides the manufacturer with 60 days notice of the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to a manufacturer's FDA-assigned labeler codes, NDC last lot expiration dates, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program.

(c) *Dispute resolution.* (1) Manufacturers may dispute applicable discounts invoiced to the manufacturer on quarterly invoices by providing notice of the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2306(b)(4) of this subpart. If payment is withheld in accordance with this paragraph, the manufacturer must notify the TPA and applicable Part D sponsors within 38 days of receipt of the applicable invoice that payment is being withheld for this reason.

(4) If the manufacturer receives an unfavorable determination from the TPA, or the dispute is not resolved within 60 calendar days of the TPA's receipt of the notice of dispute, the manufacturer may request review by the independent review entity contracted by CMS within—

(i) Thirty calendar days of the unfavorable determination; or

(ii) Ninety calendar days after the TPA's receipt of the notice of dispute if dispute is not resolved within 60 days, whichever is earlier.

(5) The independent review entity must make a determination within 90 calendar days of receipt of the manufacturer's request for review.

(6)(i) CMS or a manufacturer that receives an unfavorable determination from the independent review entity may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(7) CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the manufacturer.

§ 423.2335 Beneficiary dispute resolution.

The Part D coverage determination and appeals process as described in §§ 423.558 through 423.638 applies to beneficiary disputes involving the availability and amount of applicable discounts under the Discount Program.

§ 423.2340 Compliance monitoring and civil money penalties.

(a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.

(b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.

(c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program Agreement equal to the sum of the following:

(1) The amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide.

(2) Twenty-five percent of such amount.

(d) *Procedures for imposing civil money penalties.* If CMS makes a determination to impose a CMP described in paragraph (c) of this section, CMS sends a written notice of its decision to impose a CMP to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing (as specified in § 423.1006).

(6) Information about where to file the request for hearing.

(e) *Collection of civil money penalties imposed by CMS.* (1) When a manufacturer does not request a hearing, CMS initiates the collection of the CMP following the expiration of the timeframe for requesting an ALJ hearing as specified in § 423.1020.

(2) If a manufacturer requests a hearing and the Administrator upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP once the Administrator's decision is final.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section of 1128A of the Act) apply to CMPs under this section to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act.

§ 423.2345 Termination of Discount Program Agreement.

(a)(1) CMS may terminate the Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to the manufacturer's participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(c) Any termination does not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under § 423.2315(c) of this subpart.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: March 15, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 28, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–8071 Filed 4–2–12; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 77 Thursday,

No. 71 April 12, 2012

Part III

The President

Proclamation 8797—National Volunteer Week, 2012
Proclamation 8798—Pan American Day and Pan American Week, 2012
Proclamation 8799—National Former Prisoner of War Recognition Day, 2012

Federal Register

Vol. 77, No. 71

Thursday, April 12, 2012

Presidential Documents

Title 3—

The President

Proclamation 8797 of April 9, 2012

National Volunteer Week, 2012

By the President of the United States of America

A Proclamation

Our Nation has been profoundly shaped by ordinary Americans who have volunteered their time and energy to overcome extraordinary challenges. From the American Revolution and the Seneca Falls Convention to the everyday acts of compassion and purpose that move millions to make change in their communities, our Nation has always been at its best when individuals have come together to realize a common vision. As we continue to pursue progress, service and social innovation will play an essential role in achieving our highest ambitions—from a world-class education for every child to an economy built to last. During National Volunteer Week, we pay tribute to all who give of themselves to keep America strong, and we renew the spirit of service that has enriched our country for generations.

That spirit lives on today in countless acts of service around our country. When one of the deadliest tornados in our Nation's history touched down in Joplin, Missouri, in May 2011, thousands of volunteers stepped forward to serve their fellow citizens. They turned a university into a hospital. They repurposed doors for stretchers. They rushed food to those in need and filled trucks with donations. To date, they have committed more than half a million hours to bringing support and shelter to a community during a time of profound hardship and heartache. In Joplin and across America, we see the transformative power of service—to unite, to build, to heal.

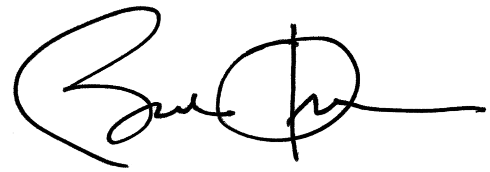
My Administration remains steadfast in our commitment to empower more Americans with tools to shape their communities. During my first 100 days in office, I was proud to sign the Edward M. Kennedy Serve America Act, a landmark national service law that laid out a strategy to link service with innovation, established the groundbreaking Social Innovation Fund, and charted the expansion of AmeriCorps. Last month, we launched FEMA Corps, a new service corps that will enhance our national capacity for disaster response and prepare its members for careers in emergency management. Through United We Serve and national service days, we continue to connect individuals young and old to new opportunities to reinvent their world through service—from fighting hunger and expanding access to healthy, affordable food to mentoring young people and fostering literacy. In all of these efforts, we are reminded how volunteer work can expand opportunity not only for those in need, but also for those who give. Service can teach valuable skills that pave the way to long-term employment and stay with volunteers throughout their careers and lives.

Service is a lifelong pursuit that strengthens the civic and economic fabric of our Nation. With every hour and every act, our lives are made richer, our communities are drawn closer, and our country is forged stronger by the dedication and generous spirit of volunteers. I encourage every American to stand up and play their part—to put their shoulder up against the wheel and help change history's course. To get started on a project near you, visit www.Serve.gov.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 15 through

April 21, 2012, as National Volunteer Week. I call upon all Americans to observe this week by volunteering in service projects across our country and pledging to make service a part of their daily lives.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of April, in the year of our Lord two thousand twelve, and of the Independence of the United States of America the two hundred and thirty-sixth.



[FR Doc. 2012–9017
Filed 4–11–12; 11:15 am]
Billing code 3295–F2–P

Presidential Documents

Proclamation 8798 of April 9, 2012

Pan American Day and Pan American Week, 2012

By the President of the United States of America

A Proclamation

In April of 1890, delegates from countries throughout the Americas gathered in Washington, D.C., united in the belief that cooperation would lead to a more peaceful, secure, and prosperous hemisphere. Demonstrating remarkable foresight and a commitment to progress, they came together to forge a community of nations that would one day become the Organization of American States—a body dedicated to the pursuit of democracy and economic opportunity for all our people. During Pan American Day and Pan American Week, we celebrate this legacy of international partnership and renew the bonds of friendship and shared responsibility that join us in common purpose.

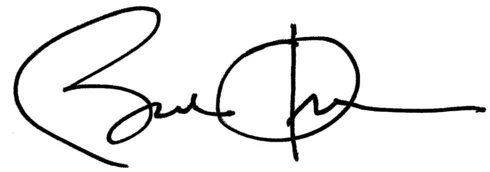
The United States is proud to be part of the inter-American community. From the shores of Canada to the cliffs of Cape Horn, our hopes are bound together—to create greater social and economic opportunity for all, to ensure safety for our citizens, to build strong and accountable democratic institutions, to secure a clean energy future. Our Nation remains committed to working together with partners across our hemisphere to achieve these goals.

Last October, I was proud to sign legislation to implement Free Trade Agreements with Panama and Colombia that will support American jobs, open new markets to our exports, and spur growth here at home and throughout the region. These Agreements strengthen our partnerships, and they reflect our commitment to supporting democracy and economic opportunity throughout the Americas. We are also working to fuel education and innovation across our hemisphere. One year ago, we announced the 100,000 Strong in the Americas initiative to encourage more of our students to study abroad in Latin America and more Latin American students to study here in the United States, fostering lifelong connections between our nations that will be keys to progress. And as we move forward, we continue to support strong democracies and democratic institutions that promote transparency in government, respect the rule of law, ensure a robust civil society, respect human rights, and deliver public services in effective and equitable ways.

This week, we gather in Cartagena, Colombia, for the Sixth Summit of the Americas. As 34 Heads of State and Government come together to chart a path toward tomorrow's horizons, let us recall that though we are stewards of unique and varied histories, our nations are partners in progress. During Pan American Day and Pan American Week, we celebrate our shared heritage, reflect on the gains we have made, and recommit to advancing the common prosperity and security of all our people.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 14, 2012, as Pan American Day and April 8 through April 14, 2012, as Pan American Week. I urge the governors of the 50 States, the governor of the Commonwealth of Puerto Rico, and the officials of the other areas under the flag of the United States of America to honor these observances with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of April, in the year of our Lord two thousand twelve, and of the Independence of the United States of America the two hundred and thirty-sixth.



[FR Doc. 2012–9018
Filed 4–11–12; 11:15 am]
Billing code 3295–F2–P

Presidential Documents

Proclamation 8799 of April 9, 2012

National Former Prisoner of War Recognition Day, 2012

By the President of the United States of America

A Proclamation

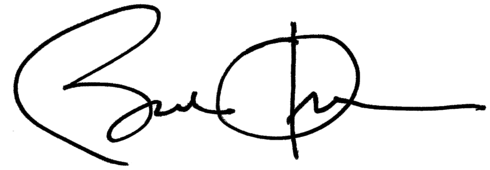
For more than 200 years, members of our Armed Forces have upheld an oath to protect and defend. In times of war, generations have answered our country's call with courage and valor, braving the peril of combat and pressing onward in the face of tremendous adversity. Their extraordinary service reflects our highest ideals, and their sacrifice will forever live on in our national memory. On National Former Prisoner of War Recognition Day, we pay solemn tribute to those patriots who gave their freedom to preserve our own.

Thousands of America's sons and daughters have suffered unspeakably as captives in foreign lands. Many prisoners of war experienced physical torture and profound anguish, subjected to inhumane treatment and cut off from their comrades, their country, and their loved ones. Some would never return. Yet, in the direst circumstances, these service members demonstrated indomitable courage and unbreakable resolve. They stood fast for what they believed in, making immeasurable sacrifices for the millions they protected. At home, spouses, children, parents, and friends called upon that same spirit of perseverance to sustain them through long periods of prayer and uncertainty.

When he chronicled the experiences of our GIs during World War II, Ernie Pyle wrote that their world can never be known to the rest of us. Though the sacrifices they made and the burdens they bore may defy our full understanding, it is our moral obligation to keep faith with our men and women in uniform, our veterans, and their families—to honor their service through the support of a grateful Nation. Today, we recognize heroes who endured one of war's most tragic costs. For them, and for all who have served, let us rededicate ourselves to fulfilling the sacred trust we share with all those who have worn the uniform of the United States of America.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 9, 2012, as National Former Prisoner of War Recognition Day. I call upon all Americans to observe this day of remembrance by honoring all American prisoners of war, our service members, and our veterans. I also call upon Federal, State, and local government officials and organizations to observe this day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of April, in the year of our Lord two thousand twelve, and of the Independence of the United States of America the two hundred and thirty-sixth.



[FR Doc. 2012–9019
Filed 4–11–12; 11:15 am]
Billing code 3295–F2–P

Reader Aids

Federal Register

Vol. 77, No. 71

Thursday, April 12, 2012

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

Reminders. Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at **http://www.regulations.gov.**

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, APRIL

CFR PARTS AFFECTED DURING APRIL

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

H.R. 473/P.L. 112–103
Help to Access Land for the Education of Scouts (Apr. 2, 2012; 126 Stat. 284)

H.R. 886/P.L. 112–104
United States Marshals Service 225th Anniversary Commemorative Coin Act (Apr. 2, 2012; 126 Stat. 286)

Last List April 2, 2012

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.